# HEALTH SERVICES AND DEVELOPMENT AGENCY DECEMBER 11, 2019 APPLICATION SUMMARY

NAME OF PROJECT:

Saint Thomas West Hospital

PROJECT NUMBER:

CN1909-039

ADDRESS:

4220 Harding Pike

Nashville (Davidson County), TN 37205

LEGAL OWNER:

Saint Thomas West Hospital

4220 Harding Pike

Nashville (Davidson County), TN 37205

**OPERATING ENTITY:** 

Not Applicable

**CONTACT PERSON:** 

Lacey Benford

(615) 284-4581

**DATE FILED:** 

September 13, 2019

PROJECT COST:

\$1,640,673

FINANCING:

Cash Reserves

**PURPOSE FOR FILING:** 

Initiation of positron emission tomography (PET)

services

#### **DESCRIPTION:**

Saint Thomas West Hospital (STW) is seeking approval to initiate cardiac PET/CT services with a purchase of a GE PET/CT scanner. The PET/CT service will be located at 4220 Harding Pike, (Davidson County), TN.

### SPECIFIC CRITERIA AND STANDARDS REVIEW:

#### POSITRON EMISSION TOMOGRAPHY SERVICES

1. Applicants proposing a new stationary PET unit should project a minimum of at least 1,000 PET procedures in the first year of service, building to a minimum of 1,600 procedures per year by the second year of service and for every year thereafter. Providers proposing a mobile PET unit should project a minimum of at least 133 mobile PET procedures in the first year of service per day of operation per week, building to an annual minimum of 320 procedures per day of operation per week by the second year of service and for every year thereafter. The minimum number of procedures for a mobile PET unit should not exceed 1,600 procedures per year if the unit is operated more than five (5) days per week. The application for mobile and stationary units should include projections of demographic patterns, including analysis of applicable population-based health status factors and estimated utilization by patient clinical diagnoses category (ICD-9).

For units with a combined utility, e.g., PET/CT units, only scans involving the PET function will count towards the minimum number of procedures.

The applicant expects to perform 2,100 PET scans in Year 1 increasing to 2,800 PET scans in Year 2. This projected volume will exceed the minimum standard of 1,000 PET procedures in Year 1 and 1,600 PET procedures in-Year 2.

It appears that this criterion will be met.

2. All providers applying for a proposed new PET unit should document that the proposed location is accessible to approximately 75% of the service area's population. Applications that include non-Tennessee counties in their proposed service areas should provide evidence of the number of existing PET units that service the non-Tennessee counties and the impact on PET unit utilization in the non-Tennessee counties, including the specific location of those units located in the non-Tennessee counties, their utilization rates, and their capacity.

The applicant notes the proposed PET service will be accessible to at least 75% of the service area population.

It appears that this criterion has been met.

3. All providers should document that alternate shared services and lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.

The applicant was not able to identify opportunities for shared services or lower cost technology available.

4. Any provider proposing a new mobile PET unit should demonstrate that it offers or has established referral agreements with providers that offer as a minimum, cancer treatment services, including radiation, medical and surgical oncology services.

The clinical applications will focus on cardiology-Rubidium dosed cardiac PET/CT scans and myocardial stress testing, and F-18-dosed myocardial viability testing.

It appears that this criterion is not applicable.

5. A need likely exists for one additional stationary PET unit in a service area when the combined average utilization of existing PET service providers is at or above 80% of the total capacity of 2,000 procedures during the most recent twelve-month period reflected in the provider medical equipment report maintained by the HSDA. The total capacity per PET unit is based upon the following formula:

Stationary Units: Eight (8) procedures per day x 250 days/year = 2,000 procedures per year

Mobile Units: Eight (8) procedures /day x 50 days/year= 400 procedures/year

The provider should demonstrate that its acquisition of an additional stationary or mobile PET unit in the service area has the means to perform at least 1,000 stationary PET procedures or 133 PET procedures per day of operation per week in the first full one-year period of service operations, and at least 1,600 stationary PET procedures or 320 PET procedures per day of operation per week for every year thereafter.

There are 10.1 PET units available in the 37-county service area. The 2018 37-county service area combined average utilization was 81% of the 1,600/unit optimal standard. The applicant projects 2,100 PET scans in Year 1 and 2,200 PET scans in Year 2, surpassing the utilization threshold of 1,000 for Year 1, and 1,600 procedures for Year 2.

It appears that this criterion is partially met.

- 6. The applicant should provide evidence that the PET unit is safe and effective for its proposed use.
  - a. The United States Food and Drug Administration (FDA) must certify the proposed PET unit for clinical use.

The PET/CT was approved more than 5 years ago.

It appears that this criterion has been met.

b. The applicant should demonstrate that the proposed PET procedures will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.

The applicant provided an architect's certification letter in Tab 9 in the application attachments.

It appears that this criterion will be met.

c. The applicant should demonstrate how emergencies within the PET unit facility will be managed in conformity with accepted medical practice.

Emergencies will be managed within the STW facility.

It appears that this criterion has been met.

d. The applicant should establish protocols that assure that all clinical PET procedures performed are medically necessary and will not unnecessarily duplicate other services.

The applicant provided policies in Tab 15 addressing the criterion.

It appears that this criterion has been met.

e. The PET unit should be under the medical direction of a licensed physician. The applicant should provide documentation that attests to the nature and scope of the duties and responsibilities of the physician medical director. Clinical supervision and interpretation services must be provided by physicians who are licensed to practice medicine in the state of Tennessee and are board certified in Nuclear Medicine or Diagnostic Radiology. Licensure and oversight for the handling of medical isotopes and radiopharmaceuticals by the Tennessee Board of Pharmacy and/or the Tennessee Board of Medical Examiners—whichever is appropriate given the setting—is required. Those qualified physicians that provide interpretation services should have additional documented experience and training, credentialing, and/or board certification in the appropriate specialty and in the use and interpretation of PET procedures.

The PET/CT unit will be under the medical direction of Dr. Dante J. Graves. A document outlining Dr. Grave's qualifications is provided in Tab 19 in the application attachments.

It appears that this criterion has been met.

f. All applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. An applicant's arrangements with its physician

medical director must specify that said physician be an active member of the subject transfer agreement hospital medical staff.

Saint Thomas West Hospital operates a full service emergency department. The medical director is an active member of the staff of STW.

It appears that this criterion has been met.

7. The applicant should provide assurances that it will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.

The applicant states it will submit data in a timely fashion as requested.

It appears that the applicant intends to meet this criterion.

- 8. In light of Rule 0720-4-.01 (1), which lists the factors concerning need on which an application may be evaluated, the HSDA may decide to give special consideration to an applicant:
  - a. Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;

All but three of the 37 PET/CT service area counties are designated by the United Sates Health Resources and Services Administration as a medically underserved area.

b. Who documents that the service area population experiences a prevalence, incidence and/or mortality from cancer, heart disease, neurological impairment or other clinical conditions applicable to PET unit services that is substantially higher than the State of Tennessee average;

According to the Tennessee Department of Health, twenty-five service area counties (68% of the total), have cardiac death rates greater than the Tennessee rate, with six exceeding the Tennessee rate by more than 150%, and another two by more than 200%.

c. Who is a "safety net hospital" or a "children's hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program and/or is a comprehensive cancer diagnosis and treatment program as designated by the Tennessee Department of Health and/or the Tennessee Comprehensive Cancer Control Coalition; or

The applicant is not a safety net or children's hospital. It appears this criterion is not applicable.

d. Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program.

The applicant contracts with all TennCare MCOs and with Medicare. The applicant projects a 5.0% TennCare and a 49% Medicare payor mix in the first year of the project.

It appears that this criterion has been met.

#### **Staff Summary**

The following information is a summary of the original application and all supplemental responses. Any staff comments or notes, if applicable, will be in bold italics.

#### **Application Synopsis**

Saint Thomas West Hospital is seeking approval for the initiation of PET/CT services at 4220 Harding Pike, Nashville (Davidson County), TN. STW proposes to replace an eleven-year-old Single Photon Emission Computed Tomography (SPECT) dual unit with a cardiac PET/CT unit. The proposed PET/CT project will provide patient cardiac medicine studies.

If approved, the applicant plans to initiate the proposed PET service in October 2020.

#### **Facility Information**

- The proposed PET/CT scanner will be located in 770 SF of renovated space in the existing nuclear medicine room located on the fourth floor in the non-invasive cardiac department.
- Minor construction and renovation totaling \$450,000 will be needed.
- The applicant will purchase a GE Discovery ST System PET/CT at a total cost of \$896,286. The expected useful life of the PET/CT is 5 years.
- A plot plan and floor plan drawing for the PET/CT pad is included as Attachments A-6B (1) and (2).
- The hours of service are expected to be 7:00 am 11:00 pm.

The Joint Annual Report for 2018 indicates that St. Thomas West Hospital was licensed for 541 beds and staffed at 395 beds. Licensed bed occupancy was 51.8% and staffed bed occupancy was 70.9%.

The following provides the Department of Health's definition of the two bed categories pertaining to occupancy information provided in the Joint Annual Reports:

- Licensed Beds The maximum number of beds authorized by the appropriate state licensing (certifying) agency or regulated by a federal agency. This figure is broken down into adult and pediatric beds and licensed bassinets (neonatal intensive or intermediate care bassinets).
- Staffed Beds The total number of adult and pediatric beds set up, staffed and in use at the end of the reporting period. This number should be less than or equal to the number of licensed beds.

#### Ownership

- Saint Thomas West Hospital is owned by Saint Thomas Health.
- Saint Thomas Health is part of Ascension, a non-profit health system and the largest Catholic health system.
- An organizational chart of Saint Thomas West Hospital is located in Attachment A-4B-2.

#### **Need**

#### **Project Need**

The applicant provides the following justification in the application:

- The proposed PET/CT cardiac service is needed to replace an eleven-yearold dual SPECT general unit. The project is needed to enhance cardiac nuclear medicine studies. According to the American Society of Nuclear Imaging, recent innovations in cardiac imaging have elevated positron emission tomography (PET) as the gold standard of care for patients with suspected or known coronary artery disease (CAD).
- According to the Intermountain Medical Center Heart Institute, overall PET more successfully identified patients with severe obstructive CAD and the need for revascularization; compared to SPECT, PET scans increased true positives and reduced false positives for severe coronary artery disease.
- SPECT cardiac stress testing at STW declined from 2,014 procedures in FY2018 to 1,879 procedures in FY2019. The proposed PET/CT unit is necessary to improve patient care and reverse the decline.
- PET imaging services for residents of the service area increased 21% from 11,773 procedures in 2016 to 14,262 in 2018.

#### Service Area Demographics

The applicant's declared primary service area consists of the following nine counties: Cheatham, Davidson, Dickson, Montgomery, Robertson, Rutherford, Sumner, Williamson, and Wilson Counties. An overview of the service area is provided as follows:

- The total population of the service area is estimated at 1,978,341 residents in calendar year (CY) 2019 increasing by approximately 6.3% to 2,103,269 residents in CY 2023.
- The overall statewide population is projected to grow by 3.2% from 2019 to 2023.
- The 65 and older population is expected to comprise approximately 14.2% of the total service area population in CY2023 compared to 18.3% statewide.
- The 65 and older population of the 9-county service area will increase by approximately 16.1% from CY2019 to CY2023 as compared to the statewide increase of 11.6% during the same period.
- The proportion of TennCare enrollees of the total service area population is 15.1%, compared with the statewide average of 20.8%.

#### Secondary Service Area

The applicant identifies 28 counties in Middle Tennessee as the secondary service area (SSA).

- The total population of the secondary service area is estimated at 807,858 residents in calendar year (CY) 2019 increasing by approximately 2.0% to 823,760 residents in CY 2023.
- The total 65+ age population (target population) is estimated to account for approximately 20.8% of the total SSA population in the year 2023 compared to 18.3% statewide.
- The number of residents enrolled in TennCare is approximately 22.4% of the total SSA population compared to 20.8% statewide.

#### Service Area Historical Utilization

There are 10.4 PET providers located in the service area. The following table reflects the PET service utilization in the 37-county proposed service area.

#### 9 Historical PET Utilization 37-County Proposed Service Area

			2016	2017	2018	<b>'16-'18</b>	2018
County	Provider	# Units in 2019	Scans	Scans	Scans	% change	% of Standard*
Coffee	Tennova Healthcare- Harton	0.1	46	22	11	-76.1%	7%
Davidson	Imaging Alliance- Nashville PET	1	1,155	1,306	1,312	+13.6%	82%
Davidson	Premier Radiology- Midtown	1	608	762	931	+53.2%	58%
Davidson	Tennessee Oncology	1	1,218	1,244	1,340	+10.0%	84%
Davidson	Tri-Star Centennial Medical Center	1	765	974	1,155	+51.0%	72%
Davidson	Vanderbilt University Medical Center (2 Units)	2	3,852	3,313	3,561	-7.6%	111%
Maury	Maury Regional Medical Center	0.4	604	691	662	+9.6%	103%
Montgomery	Tennova-Healthcare- Clarksville	0.2	334	316	399	+19.5%	125%
Putnam	Cookeville Regional Medical Center	1	656	708	718	+9.5%	45%
Robertson	NorthCrest Medical Center	0.2	174	137	185	+6.3%	58%
Rutherford	Tennessee PET Scan Center	1	1,932	2,126	2,223	+15.1%	140%
Sumner	Diagnostic Center at Sumner Station	1	265	331	439	+65.7%	27%
Williamson	Williamson Medical Center	0.2	164	178	200	+22.0%	63%
	Total	10.1	11,773	12,108	13,136	+11.6%	81%

Source: HSDA Medical Equipment Registry

<sup>\*</sup>The State Health Plan Certificate of Need PET Standards and Criteria indicate "applicants proposing a new stationary PET unit should project a minimum of at least 1,000 PET procedures in the first year of service, building to 1,600 procedures per year by the second year of service and every year thereafter."

- Overall, PET scanners in the proposed service area attained 81% of the 1,600 optimal PET procedure standard in 2018.
- The following PET providers met the optimal PET utilization standard in 2018: Vanderbilt University Medical Center (111%), Maury Regional Medical Center (103%), Tennova Healthcare-Clarksville (125%), and Tennessee PET Scan Center (140%).
- The chart above indicates that PET volumes in the service area increased 11.6% from 11,773 procedures in 2016 to 13,136 in 2018.

#### Applicant's Projected Utilization

The following chart reflects the projected PET scans in Year 1 and Year 2.

Saint Thomas West Hospital-Projected Scans								
Year One Year Two								
	(2020)	(2021)						
PET/CT Scans	PET/CT Scans 2,100 2,800							

Source: CN1909-035, Page 44R

- The applicant projects 2,100 PET scans in Year 1 increasing 33% to 2,800 scans in Year 2.
- The applicant's projections in Year 2 are based on a 27% capture rate of the inpatient cardiac discharges. In 2018, STH reported 10,470 cardiac inpatient discharges.

#### **ECONOMIC FEASIBILITY**

#### **Project Cost**

Major costs of the \$1,640,673 total estimated project cost are as follows:

- Fixed Equipment- \$896,286 or approximately 54.6% of the total project cost.
- Construction \$450,000 or approximately 27.4% of total cost.
- Contingency Fund-\$126,828 or approximately 7.7% of total cost.
- For other details on Project Cost, see the Project Cost Chart on page 27 of the application.
- The total estimated renovation cost of the 770 square foot (SF) facility is expected to be \$584.42/SF, which is above the 3<sup>rd</sup> quartile cost of \$227.45 /sq. ft. for previously approved hospital CON projects from 2016-2018.
- The renovation cost is above the 3<sup>rd</sup> quartile for hospital renovation cost because the imaging space requires expensive shielding and installation, there are concentrated weight loads, and specialized electrical systems. All the renovation costs are spread over a small 770 SF footprint creating a higher cost per square foot.

#### **Financing**

The proposed project will be financed through cash reserves. A September 10, 2019 letter from the Chief Financial Officer of Saint Thomas West Hospital certifies that existing cash reserves will fund the proposed project.

Review of the Consolidated Balance Sheet for Ascension revealed total current assets of \$5,513,790,000 including cash and cash equivalents of \$850,958,000 and total current liabilities of \$5,388,491,000 for the period ending June 30, 2018. As a result, the Current Ratio was approximately 1.02 to 1.0 for the period.

Note to Agency members: Current ratio is a measure of liquidity and is the ratio of current assets to current liabilities, which measures the ability of an entity to cover its current liabilities with its existing current assets. A ratio of 1:1 would be required to have the minimum amount of assets needed to cover current liabilities.

#### **Net Operating Margin Ratio**

• The applicant projects a net operating margin ratio for the project of approximately 60.6% in Year 1 and 66.7% in Year 2.

Note to Agency Members: The net operating margin demonstrates how much revenue is left over after all the variable or operating costs have been paid.

#### Capitalization Ratio

• Ascension's capitalization ratio as of June 30, 2018 was 23.6%.

Note to Agency Members: The capitalization ratio measures the proportion of debt financing in a business's permanent financing mix.

#### **Historical Data Chart**

Saint Thomas West Hospital

- According to the Historical Data Chart, Saint Thomas West Hospital experienced a net balance (net operating income – [annual principal debt repayment + annual capital expenditures]) of \$40,742,000 for 2017; \$49,184,000 for 2018; and \$47,625,000 for 2019.
- Saint Thomas West Hospital Free Cash Flow (Net Balance + Depreciation) of \$59,326,000 for 2017; \$67,959,000 for 2018; and \$66,475,000 for 2019.
- Since the applicant is applying for the establishment of a PET/CT service, a project only historical data chart is not applicable.

#### **Projected Data Chart**

#### Total Facility

The Projected Data Chart for STW in total reflects \$2,392,767,000 in total gross operating revenue in Year 1 increasing by approximately 4.9% to \$2,510,466,000 in Year 2. The Projected Data Chart reflects the following:

- Net operating revenue after bad debt, charity care, and contractual adjustments is expected to average approximately 20.2% of gross revenue in Year 1 and 19.7% in Year 2 of the project.
- The net balance is projected to equal \$43,377,000 in Year 1 increasing to \$45,057,000 in Year 2.

#### Proposed PET/CT

The Projected Data Chart for the applicant's proposed PET/CT reflects \$14,787,601 in total gross operating revenue on 2,100 scans in Year 1 (\$7,041/scan) increasing to \$19,716,801 on 2,800 procedures in Year 2. The Projected Data Chart reflects the following:

- Net operating revenue after bad debt, charity care, and contractual adjustments is expected to average approximately 19% in Year 1 and 17% in Year 2 of the proposed project's gross operating revenue.
- The net balance is projected to equal \$1,510,012 in Year 1 increasing to \$2,041,150 in Year 2.

#### Charges

A summary of the applicant's charges for Year 1 of the project is as follows:

- The proposed average gross charge is \$7,042 and net charge is \$1,338 per PET procedure in Year 1.
- The \$7,042 average gross charge is between the median PET charge of \$5,993 and the third quartile charge of \$7,504 for PET Scanners operating in Tennessee during 2018.

#### Medicare/TennCare Payor Mix

• The applicant participates in the Medicare and TennCare programs. The applicant contracts with the following TennCare MCOs: AmeriGroup, BlueCare, United Healthcare Community Plan, and TennCare Select.

The applicant's projected payor mix for Year 1 (2020) is as follows:

Payor Source	Gross Revenue	% Gross Revenue
Medicare/Medicare Managed Care	\$7,245,925	49.0%
TennCare/Medicaid	\$739,380	5.0%
Commercial/Other Managed Care	\$5,619,288	38.0%
Self-Pay	\$1,035,132	7.0%
Champus, Workgroup	\$147,876	1.0%
TOTAL	\$14,787,601	100.0%
Charity Care	\$295,752	

Source: CN1909-039, Page 37-R.

## PROVIDE HEALTHCARE THAT MEETS APPROPRIATE QUALITY STANDARDS

#### Licensure

- The Tennessee Department of Health licenses STW.
- STW holds a radioactive material license from the Tennessee Department of Environment and Conservation.

#### Certification

Medicare and Medicaid certify STW.

#### Accreditation

• The Joint Commission accredits STW.

#### Other Quality Standards

- In the application the applicant commits to obtaining and/or maintaining the following:
  - Staffing levels comparable to the staffing chart presented in the CON application
  - o Licenses in good standing
  - o TennCare/Medicare certifications
  - o Three years compliance with federal and state regulations
  - o Has not been decertified in last three years
  - o Self-assessment and external peer assessment processes
  - o Data reporting, quality improvement, and outcome/process monitoring systems
  - Accreditation by any organization approved by Centers for Medicare and Medicaid Services (CMS) and other nationally recognized programs.

# CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTHCARE

#### **Agreements**

 The list of Saint Thomas agreements are listed on page 45 and in Tab 14-Attachment Section B-Economic-7 of the application.

#### **Impact on Existing Providers**

 The applicant indicates the proposed project should not impact the existing PET/CT service providers in the service area. The service area PET provider historical annual PET growth is 9.63%, and is projected to average 1,695 procedures per scanner (includes recently approved PET project) by the year 2023.

#### Staffing

The applicant's proposed direct patient care staffing in Year 1 includes the following:

Position Type	Year One
Registered Nurse/Nuclear Tech	4.0
Total	4.0

Source: CN1909-039, Page 38

Corporate documentation, real estate lease, and detailed demographic information are on file at the Agency office and will be available at the Agency meeting.

Should the Agency vote to approve this project, the CON would expire in three years.

#### CERTIFICATE OF NEED INFORMATION FOR THE APPLICANT

There are no other Letters of Intent, pending applications, or outstanding Certificates of Need for this applicant.

Saint Thomas Healthcare has an interest in this project and the following:

#### **Denied Applications**

Saint Thomas West Hospital CN1811-046D, was denied at the February 27, 2019 Agency meeting to initiate adult liver transplant services. The estimated project cost was \$940,000. Reason for Denial: The applicant has not established need. There appears to be adequate capacity for transplant services. There has not been anyone in particular who needed a transplant that could not get a transplant at Vanderbilt. No one has come forward and said they could not get a transplant because they were denied being put on a wait list at Vanderbilt. It does not contribute to the orderly development of healthcare with the changes

in how livers are going to be distributed. The applicant will not be able to reach the volumes it needs to reach in order to achieve the outcomes that were talked about. Volume and outcomes go hand in hand, and it will have a negative impact on the existing transplant program.

Saint Thomas Midtown Hospital (Emergency Department at Brentwood), CN1412-049D, was denied at the March 25, 2015 Agency meeting for the establishment of a satellite emergency department facility with 8 treatment rooms at 791 Old Hickory Boulevard, Brentwood (Davidson County), TN. The facility was planned to be physically connected to Premier Radiology. The estimated project cost was \$6,757,172.00. Reason for Denial: The application did not meet the statutory criteria. The decision was reached following consideration of the written report of the Department of Health/Office of Health Policy, the State Health Plan, the general criteria established by Health Services and Development Agency rules, and all evidence presented in the application.

Middle Tennessee Imaging, LLC d/b/a Premier Radiology, CN1605-016D, was denied at the October 26, 2016 Agency meeting for the establishment of an outpatient diagnostic center (ODC), acquisition of fixed magnetic resonance imaging (MRI) equipment, and the initiation of MRI services at 980 Professional Park Drive, Suite E in Clarksville (Montgomery County). The estimated project cost was \$941,648.00. Reason for Denial: The application did not meet the statutory criteria. The imaging service is located in Clarksville (Montgomery County); there was not an opportunity to examine the need of the other 19 counties in the service area.

#### Outstanding Certificates of Need

Saint Thomas Rehabilitation Hospital, LLC, CN1905-019A, has an outstanding Certificate of Need that will expire October 1, 2022. The project was approved at the August 28, 2019 Agency meeting for the for the construction of a 51,947 SF 40 bed freestanding rehabilitation hospital containing all private patient rooms to be located on the campus of St. Thomas Midtown Hospital (Midtown). The estimated project cost is \$47,934,213. Project Status Update: The project was recently approved.

Tenn SM, LLC d/b/a Providence Surgery Center, CN1903-008, has an outstanding Certificate of Need that will expire on October 1, 2021. The project was approved at the August 28, 2019 Agency meeting for the relocation of an existing multi-specialty ambulatory surgical treatment center (ASTC) from 5002 Crossing Circle, Suite 110, Mt. Juliet (Wilson County), TN, approximately one mile to an unaddressed location at SW Corner of Belinda Parkway and Providence Trail intersection, Mt. Juliet (Wilson County), TN. The ASTC will also add one procedure room so that there will be two operating rooms and two procedure rooms. The estimated project cost is \$8,082,908. Project Status Update: The project was recently approved.

Cumberland Behavioral Health, CN1806-022A, has an outstanding Certificate of Need that will expire December 1, 2021. The project was approved at the October 24, 2018 Agency meeting for the establishment of a 76 bed mental health hospital at 300 Great Circle Road, Nashville (Davidson County), TN. The hospital will contain 40 adult inpatient psychiatric beds and 36 geriatric inpatient psychiatric beds. Saint Thomas West Hospital will close its 24 bed psychiatric unit and surrender those beds. The estimated project cost is \$32,216,800. Project Status Update: A November 12, 2019 status update from a project representative indicated groundbreaking took place in August 2019, design is under review by the State, and site preparation has begun.

Northridge Surgery Center, CN1806-023A, has an outstanding Certificate of Need that will expire December 1, 2020. The project was approved at the October 24, 2018 Agency meeting for the relocation of its existing multi-specialty ambulatory surgical treatment center (ASTC) with 5 operating rooms and 1 procedure room from 647 Myatt Drive in Madison (Davidson County), TN, 37115 to leased space in a new facility to be constructed on a 1.87-acre site that is part of a 17-acre parcel located at 601 Saundersville Road, Hendersonville (Sumner County), TN, 37075, a distance of approximately 9.5 miles. When complete, the new replacement ASTC will include three operating rooms and one procedure room, a reduction of two operating rooms from the applicant's existing facility. The estimated project cost is \$17,141,813. Project Status Update: An annual progress report received October 5, 2019 from a representative of the applicant indicated that construction bids are being reviewed with a potential start on construction being first quarter of 2020. (Note: This project is under appeal with a hearing date of March 2020.)

MTI dba Premier Radiology, CN1805-021A, has an outstanding Certificate of Need that will expire on October 1, 2020. The project was approved at the August 22, 2018 Agency meeting for the establishment of an Outpatient Diagnostic Center, initiation of MRI services, and acquisition of a fixed 1.5T MRI unit in a new building under construction at 3754 Murfreesboro Pike, Antioch (Davidson County), TN. The estimated project cost is \$3,558,788. Project Status Update: A status update was requested by November 12, 2019 from a project representative but was not received. A second request was made on November 14, 2019 and there was no response. However, the last report from a project representative in a 5/31/19 email indicated suite buildout for the project was currently in process. The applicant was targeting a mid-August 2019 opening. Note to Agency members: According to the Department of Health Licensure Website, this ODC has not yet opened.

Middle Tennessee Imaging, LLC d/b/a Premier Radiology, CN1803-014A, has an outstanding Certificate of Need that will expire August 1, 2020. The project was approved at the June 27, 2018 Agency meeting for the establishment of an outpatient diagnostic center (ODC), the initiation of MRI services, and the acquisition of a fixed 1.5 Tesla MRI unit and fixed 16 slice CT unit at a new building under construction at

17 the ODC will provide x-ray, mammography, and ultrasound services, which will support primary care services at the Saint Thomas Medical Partners-Gallatin Care Center. The estimated project cost is \$6,078,275. Project Status Update: A status update was requested by November 12, 2019 from a project representative but was not received. A second request was made on November 14, 2019 and there was no response. However, per an email from a project representative dated February 7, 2019, the project construction was scheduled to be completed by April 30, 2019 with an expected opening around May 15, 2019. This project's approval is currently being appealed by Sumner Regional Medical Center. Note to Agency members: According to the Department of Health Licensure website, this ODC was originally licensed on August 15, 2019. This applicant must still file a Final Project Progress Report.

Saint Thomas Surgery Center New Salem, CN1707-022A, has an outstanding Certificate of Need that will expire December 1, 2019. The project was approved at the October 25, 2017 Agency meeting for the establishment of a multi-specialty ambulatory surgical treatment center (ASTC) with two operating rooms and one procedure room located at 2779 New Salem Road, Murfreesboro (Rutherford County), TN 37128. The project will involve the construction of 13,000 square feet of new ASTC space that will be leased by the applicant. The estimated project cost is \$16,228,645. Project Status Update: A July 19, 2019 status update from a project representative indicated land has been purchased with construction to begin in the fourth quarter of 2019. The CON Holder was granted a 2-year extension to December 1, 2021 from the Agency at its August 28, 2019 meeting.

Saint Thomas Rutherford Hospital, CN1707-021A, has an outstanding Certificate of Need that will expire on December 1, 2020. The project was approved at the October 25, 2017 Agency meeting for the addition of 72 beds which will increase the licensed bed capacity from 286 beds to 358 beds. The hospital is located at 1700 Medical Center Parkway, Murfreesboro (Rutherford County), TN 37129. The estimated project cost is \$47,478,943. Project Status Update: Per an Annual Progress Report, dated October 15, 2019, construction is continuing with an anticipated completion date of April 2020.

#### <u>CERTIFICATE OF NEED INFORMATION FOR OTHER SERVICE AREA</u> <u>FACILITIES:</u>

There are no other Letters of Intent or denied applications for other health care organizations in the service area proposing this type of service.

**TriStar Skyline Medical Center, CN1909-035**, has a pending application scheduled to be heard at the December 11, 2019 Agency meeting for the initiation of mobile PET services up to 2 days per week. The mobile PET service will be located at 3441 Dickerson Pike, (Davidson County), TN. **The estimated project cost is \$610,000**.

#### Outstanding Certificates of Need

**Lebanon PET Scan Center, CN1905-018**, has an outstanding Certificate of Need that will expire on October 1, 2021. The project was approved at the August 28, 2019 Agency meeting for the establishment of an outpatient diagnostic center (ODC) and the initiation of a Positron Emission Tomography (PET) service in an existing onestory medical office building located in Hartmann Commons, 103 Physicians Way, Lebanon, TN, (Wilson County), Tennessee 37090. The project will be licensed as an Outpatient Diagnostic Center limited to PET studies. The estimated project cost is \$3,421,663. *Project Status Update: The project was recently approved.* 

PLEASE REFER TO THE REPORT BY THE DEPARTMENT OF HEALTH, DIVISION OF HEALTH STATISTICS, FOR A DETAILED ANALYSIS OF THE STATUTORY CRITERIA OF NEED, ECONOMIC FEASIBILITY, HEALTH CARE THAT MEETS APPROPRIATE QUALITY STANDARDS, AND CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE IN THE AREA FOR THIS PROJECT. THAT REPORT IS ATTACHED TO THIS SUMMARY IMMEDIATELY FOLLOWING THE COLOR DIVIDER PAGE.

*PME* 12/02/2019

## **LETTER OF INTENT**



### State of Tennessee 20 Health Services and Development Agency

Andrew Jackson Building, 9<sup>th</sup> Floor 502 Deaderick Street Nashville, TN 37243

www.tn.gov/hsda

Phone: 615-741-2364

Fax: 615-741-9884

#### **LETTER OF INTENT**

The Publication of Intent is to be published	ed in the	The Tennessean (Name of Newspaper)	which is a newspaper
of general circulation in		/·····	09/10 20 <u>19,</u> (Month / day) (Year)
for one day.			, , ,
This is to provide official notice to the accordance with T.C.A. § 68-11-1601 that:	Health Service et seq., and the	es and Development e Rules of the Health	Agency and all interested parties, in Services and Development Agency
Saint Thomas West Hospital			Hospital Provider
(Name of Applicant)			Facility Type-Existing)
owned by: Saint Thomas Health		_with an ownership t	ype of not-for-profit
and to be managed by: Saint Thomas	West Hospital	intends to file an ap	pplication for a Certificate of Need
for [PROJECT DESCRIPTION BEGINS HERE]: the	e purchase of a	Cardiac PET/CT an	d the initiation of Cardiac PET/CT
services at Saint Thomas West Hospi	tal located at 4	220 Harding Pike in	Nashville, TN, 37205 (Davidson
County). The project involves 770 so	quare feet of r	enovation to the ho	spital. Major medical equipment
includes the purchase of a Cardiac Pl	ET/CT scanner	. No licensed beds	are involved. Total project costs
are estimated to be \$1,640,673.			
The anticipated date of filing the applica	tion is: Septem	per 13, 2019	
The contact person for this project is	Lacey Ber (Contact Na		<u>Director, Strategy</u> (Title)
who may be reached at: Saint Th	omas Health y Name)	102	Woodmont Blvd., Suite 700 (Address)
Mashville /	TN	37205	615 / 284-4581
(Sity) 1 1	(State)	(Zip Code)	(Area Code / Phone Number)
(Signature)		(Date)	Lacey.Benford@ascenion.org (E-mail Address)
The Letter of Intent must be filed in trip	icate and receiv	ed between the first	and the tenth day of the month. If the

The Letter of Intent must be <u>filed in triplicate</u> and <u>received between the first and the tenth</u> day of the month. If the last day for filing is a Saturday, Sunday or State Holiday, filing must occur on the preceding business day. File this form at the following address:

Health Services and Development Agency Andrew Jackson Building, 9<sup>th</sup> Floor 502 Deaderick Street Nashville, Tennessee 37243

The published Letter of Intent must contain the following statement pursuant to T.C.A. § 68-11-1607(c)(1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

# Application (Copy)

# Saint Thomas West Hospital Nashville (Davidson Co.)

CN1909-039



#### State of Tennessee Health Services and Development Agency

Andrew Jackson Building, 9th Floor, 502 Deaderick Street, Nashville, TN 37243 www.tn.gov/hsda Phone: 615-741-2364 Fax: 615-741-9884

#### **CERTIFICATE OF NEED APPLICATION**

#### **SECTION A: APPLICANT PROFILE**

#### **IDENTIFYING INFORMATION**

1.	Name of Facility, Agency, or Institution						
	Saint Thomas West Hospital Name						
	4220 Harding Pike Street or Route		-		<u>idson</u> unty	_	
	Nashville City	Tennessee State	<u>:</u>		205 Code	<del></del> 9	
	Website address: www.sthealth.com						
	The facility's name and address <u>must be</u> istent with the Publication of Intent.	the name and	address	of the	project	and	must be
2.	Contact Person Available for Responses	to Questions					
	Lacey Benford Name		Dire	ector, S Title	trategy		
	Saint Thomas Health Company Name		L <u>acey.bei</u> E	nford@ mail ad		on.org	9
	102 Woodmont Blvd., Suite 700 Street or Route	Nashville City	TN State		37205 Zip Code		
	Authorized Representative Association with Owner	615-284-4581 Phone Numbe					

Please answer all questions on 8½" X 11" white paper, clearly typed and spaced, single sided, in order and sequentially numbered. In answering, please type the question and the response. All questions must be answered. If an item does not apply, please indicate "N/A" (not applicable). Attach appropriate documentation as an Appendix at the end of the application and reference the applicable Item Number on the attachment, i.e., Attachment A.1, A.2, etc. The last page of the application should be a completed signed and notarized affidavit.

#### 3. EXECUTIVE SUMMARY

#### A. Overview

Please provide an overview not to exceed three pages in total explaining each numbered point.

1) Description – Address the establishment of a health care institution, initiation of health services, bed complement changes, and/or how this project relates to any other outstanding but unimplemented certificates of need held by the applicant;

**RESPONSE**: As the flagship of the Saint Thomas Health cardiology service line, Saint Thomas West Hospital ("STW") is proposing to replace an eleven year old dual SPECT general unit with a cardiac PET/CT scanner. This project is being undertaken to enhance cardiac nuclear medicine studies. Other alternatives are not clinically appropriate for meeting patient needs.

Saint Thomas Health is a family of Tennessee hospitals and physician practices united by a single mission: to provide spiritually centered, holistic care that sustains and improves the health of the communities we serve. As a part of Ascension Health, one of the largest not-for-profit health care systems in the United States, it is committed to healing and dedicated to service, especially to persons who are poor or needy, reflecting the spiritual core of our mission, vision and values.

Saint Thomas Health is comprised of nine hospitals in middle Tennessee. Saint Thomas Medical Partners is a physician-led medical group providing primary care, specialty services, medical imaging, outpatient services and community-based medical practices through middle Tennessee and southern Kentucky.

Together, these entities are under Ascension, a faith-based healthcare organization dedicated to transformation through innovation across the continuum of care. The proposed project introduces a new service within the continuum of care to Tennessee residents with the values and mission of a faith-based perspective.

#### 2) Ownership structure;

**RESPONSE:** STW is owned by Saint Thomas Health. Saint Thomas Health is part of Ascension, the largest non-profit health system in the United States and the world's largest Catholic health system.

#### 3) Service area;

**RESPONSE:** The service area for STW's proposed PET/CT program consists of a geographic area that includes the majority of middle Tennessee's counties. STW has defined its primary service area as nine Tennessee counties, including Davidson County and eight surrounding counties. It has included another 28 counties in middle Tennessee as its secondary service area. Together, these 37 counties will account for approximately 87% of STW's proposed PET/CT scans.

In 2019, the total service area had an estimated population of 2,786,199. Official sources indicate that the service area population will grow by approximately 5.1% or 140,830 persons, by 2023. This is significantly higher growth than the 3.2% projected for Tennessee.

Given these population growth projections alone, demand for PET/CT services is expected to increase.

Existing similar service providers;

RESPONSE: As illustrated in Section B, the 10.4 existing PET/CT scanners in the service area averaged 1,164 procedures per scanner in 2017. While this is less than the 1,600 procedure minimum, PET/CT utilization has been increasing at nearly 10% per year. At the historical 9.63% annual growth rate, which includes non-resident utilization, the existing PET/CT scanners in the service area are projected to average 2,021 procedures per scanner by the 2023 planning horizon. Even including the recently approved PET/CT scanner for Lebanon PET Scan Center and this proposed STW PET/CT scanner, 2023 PET/CT utilization is projected to average 1,695 procedures per scanner. This exceeds the 80% minimum requirement.

In addition, the proposed STW PET/CT scanner is a cardiac scanner whereas many others are typically used in the field of oncology.

5) Project cost;

**RESPONSE:** STW has existing space for the PET/CT scanner, therefore only minor construction and renovation totaling \$450,000 will be required. The cost of the fixed PET/CT scanner itself is \$896,286. Total project costs are \$1,640,673, including contingencies, minor equipment and furnishings. STW's proposal is a very cost-effective approach to developing enhanced cardiac imaging services.

6) Funding;

**RESPONSE:** Funding for the project will come from existing cash reserves at Saint Thomas Health.

7) Financial Feasibility including when the proposal will realize a positive financial margin; and

<u>RESPONSE</u>: This proposal will realize a positive financial margin in its first year of operation.

8) Staffing.

**RESPONSE:** STW has existing nuclear imaging capabilities and staffing to draw upon to obtain the 4.0 additional FTEs required for this project.

#### B. Rationale for Approval

A certificate of need can only be granted when a project is necessary to provide needed health care in the area to be served, can be economically accomplished and maintained, will provide health care that meets appropriate quality standards, and will contribute to the orderly development of adequate and effective health care in the service area.

Provide a brief description of how the project meets the criteria necessary for granting a CON using the data and information points provided in Section B of the application.

#### 1) Need;

<u>Response</u>: As the flagship of the Saint Thomas Health cardiology service line, Saint Thomas West Hospital ("STW") is proposing to replace an eleven year old dual SPECT general unit with a cardiac PET/CT scanner. This project is being undertaken to enhance cardiac nuclear medicine studies. Other alternatives are not clinically appropriate for meeting patient needs.

This project has the support of the STW medical staff, including a number of interventional, noninvasive and imaging cardiologists. Please refer to the letters of support in TAB 22.

#### 2) Economic Feasibility;

**RESPONSE:** The project will be funded from the cash reserves of STW, Saint Thomas Health and Ascension. This project will realize a positive financial margin in its first year of operation.

#### 3) Quality Standards;

**RESPONSE:** STW has existing nuclear imaging services. These capabilities will be leveraged to initiate and maintain a quality cardiac PET/CT service. Replacing an eleven year old dual SPECT general unit with a cardiac PET/CT scanner will enhance the quality of patient care.

4) Orderly Development of adequate and effective health care.

**RESPONSE:** As illustrated in Section B, the 10.4 existing PET/CT scanners in the service area averaged 1,164 procedures per scanner in 2017. While this is less than the 1,600 procedure minimum, PET/CT utilization has been increasing at nearly 10% per year. At the historical 9.63% annual growth rate, which includes non-resident utilization, the existing PET/CT scanners in the service area are projected to average 2,021 procedures per scanner by the 2023 planning horizon. Even including the recently approved PET/CT scanner for Lebanon PET Scan Center and this proposed STW PET/CT scanner, 2023 PET/CT utilization is projected to average 1,695 procedures per scanner. This exceeds the 80% minimum requirement.

This project is also consistent with three of the four special considerations specified in the standards and criteria for PET services, including services to medically underserved populations, populations at substantially higher risk of death due to heart disease and the TennCare and Medicare populations.

#### C. Consent Calendar Justification

If Consent Calendar is requested, please provide the rationale for an expedited review.

A request for Consent Calendar must be in the form of a written communication to the Agency's Executive Director at the time the application is filed.

**RESPONSE:** Not Applicable

#### 4. PROJECT DETAILS

A.	Owner of the Facility, Agency or Institut	tion	
	Saint Thomas West Hospital Name		615-222-2111 Phone Number
	4220 Harding Pike Street or Route		Davidson County
	Nashville	TN	37205
	City	State	Zip Code
В.	Type of Ownership of Control (Check O	ne)	
	<ol> <li>Sole Proprietorship</li> <li>Partnership</li> </ol>	6) Government	(State of TN ordivision)
	3) Limited Partnership	7) Joint Ventur	e
	4) Corporation (For Profit)	8) Limited Liabi	ity Company
	5) Corporation (Not-for-	9) Other (Spec	ify)
	Profit)		
Sec Sec Des stru the enti	tence. Please provide documentation of the retary of State's web-site at <a href="https://tnbear.t.">https://tnbear.t.</a> tion A-4AB. RESPONSE: See TAB 1.  In the existing or proposed ownership cure organizational chart. Explain the corporownership structure relate to the applicant. And the each member's percentage of ownership cect) interest. RESPONSE: See TAB 2, ATTACH	structure of the apple rate structure and the As applicable, identify hip, for those member	ngSearch.aspx. Attachment cant, including an ownership manner in which all entities of the members of the ownership
5.	Name of Management/Operating Entity	(If Applicable)	
	Not Applicable		
	Name		
	Street or Route		County
	City	State	Zip Code
	Website address:		
a dr to b met	new facilities or existing facilities without aft management agreement that at least include provided, the anticipated term of the agreement hodology and schedule. For facilities with exicuted final contract. Attachment Section	udes the anticipated s ment, and the anticipa isting management ag	cope of management services ted management fee payment

#### 6A. Legal Interest in the Site (Check the appropriate line and submit the following documentation) The legal interest described below must be valid on the date of the Agency consideration of he certificate of need application. **Ownership** (Applicant or applicant's parent company/owner) Submit a copy of the title/deed. **Lease** (Applicant or applicant's parent company/owner) Attach a fully executed lease that includes the terms of the lease and the actual lease expense. **Option to Purchase** Attach a fully executed Option that includes the anticipated purchase price **Option to Lease** Attach a fully executed Option that includes the anticipated terms of the Option and anticipated lease expense

Check appropriate line above: For applicants or applicant's parent company/owner that currently own the building/land for the project location, attach a copy of the title/deed. For applicants or applicant's parent company/owner that currently lease the building/land for the project location, attach a copy of the fully executed lease agreement. For projects where the location of the project has not been secured, attach a fully executed document including Option to Purchase Agreement, Option to Lease Agreement, or other appropriate documentation. Option to Purchase Agreements <u>must include</u> anticipated purchase price. Lease/Option to Lease Agreements <u>must include</u> the actual/anticipated term of the agreement <u>and</u> actual/anticipated lease expense. The legal interests described herein <u>must be valid</u> on the date of the Agency's consideration of the certificate of need application.

Attachment Section A-6A RESPONSE: See TAB 3.

- **6B.** Briefly describe the following and attach the requested documentation on an 8 ½" x 11" sheet of white paper, legibly labeling all requested information.
  - 1) Plot Plan must include:

Other (Specify)

- a) Size of site (in acres);
- b) Location of structure on the site;
- c) Location of the proposed construction/renovation; and
- d) Names of streets, roads or highway that cross or border the site.

RESPONSE: See TAB 4, ATTACHMENT SECTION A-6B-1 (26.8 acres).

	2)	Floor Plan – If the facility has multiple floor page is needed, label each page.	rs, s	ubmit one page per floor. If more than o	ne
		<ul> <li>a) Patient care rooms (private or semi-private)</li> <li>b) Ancillary areas</li> <li>c) Equipment areas <u>Response</u>: See TAB 5,</li> <li>d) Other (specify)</li> </ul>			
Att	3) achm	Public Transportation Route - Describe the routes, if any, and to any highway or majo accessibility of the proposed site to patients nent Section A-6B-1 a-d, 6B-2, 6B-3. RESPONS	r ro s/cli	ad developments in the area. Describe tents.	
7.	Typ	pe of Institution (Check as appropriatemo	re t	han one response may apply)	
	A. B. C. D. E. F.	Home Health Agency Hospice Mental Health Hospital Intellectual Disability	H I. J. K. L.	Nursing Home Outpatient Diagnostic Center Rehabilitation Facility Residential Hospice Nonresidential Substitution- Based Treatment Center for Opiate Addiction Other (Specify)	-
		Institutional Habilitation Facility ICF/IID		·	
8.	Pur	rpose of Review (Check appropriate lines(s	) — I	more than one response may apply)	
	A. B. C.	Institution Change in Bed Complement Initiation of Health Care Service as Defined in TCA 68- 11-1607(4) (Specify) PET/CT X Relocation and/or	G. H. I. J. K.	MRI Unit Increase Satellite Emergency Department Addition of ASTC Specialty Addition of Therapeutic Catheterization Other (Specify) PET/CT  X	=
	E. F.	Replacement Initiation of MRI Initiation of Pediatric MRI			
9.	Med	dicaid/TennCare, Medicare Participation			
	X	CO Contracts [Check all that apply]  C_AmeriGroup _X_United Healthcare Commi	unity	Plan <u>X</u> BlueCare <u>X</u> TennCare	
		dicare Provider NumberHospital 440082			
	Med	dicaid Provider Number Hospital 440052			
		Certification TypeGeneral Hospital			
	If a	new facility, will certification be sought for M	ledi	care and/or Medicaid/TennCare?	
	Med	dicareYesNoN/A Medicaid/Tenr	пСа	reYesNoN/A	

#### 10. Bed Complement Data

A. Please indicate current and proposed distribution and certification of facility beds.

		Current Licensed	Beds Staffed	Beds Proposed	*Beds Approved	**Beds Exempted	TOTAL Beds at Completion
1)	Medical	431	299				431
2)	Surgical	300	30				
3)	ICU/CCU	86	86				86
4)	Obstetrical				-		
5)	NICU	-	2	<del></del> .	-		
6)	Pediatric	0					
7)	Adult Psychiatric			•	-		
8)	Geriatric Psychiatric	24	15				0
9)	Child/Adolescent Psychiatric					-	
10)	Rehabilitation	-		<u> </u>		<del>72 - 2</del> 0	
11)	Adult Chemical Dependency	L		-	:		
12)	Child/Adolescent Chemical Dependency	3 <del></del>	-		-	1	
13)	Long-Term Care Hospital				-		-
14)	Swing Beds	-	-		•	Re	***************************************
15)	Nursing Home – SNF (Medicare only)	c <del>i</del>	<del></del>	***************************************	<del></del>		***************************************
16)	Nursing Home – NF (Medicaid only)	-				-	
17)	Nursing Home – SNF/NF (dually certified Medicare/Medicaid)	-	<del></del>		<del>2,</del>		
18)	Nursing Home – Licensed (non-certified)		-	( <del></del>	***************************************		( <del></del>
19)	ICF/IID		-	-	<del></del>		· <del></del>
20)	Residential Hospice		====	(	<del>-</del>		·
TO	ral	541	400	:	-24		E47
*Be	ds approved but not yet in service			% per 3 year p			517

**B.** Describe the reasons for change in bed allocations and describe the impact the bed change will have on the applicant facility's existing services.

**C.** Please identify all the applicant's outstanding Certificate of Need projects that have a licensed bed change component. If applicable, complete chart below.

CON Number(s)	CON Expiration Date	Total Licensed Beds Approved
CN1806-022A	¥	-24
<u> </u>		
<del></del>		4

**11. Home Care Organizations** – Home Health Agency, Hospice Agency (excluding Residential Hospice), identify the following by checking all that apply: – **RESPONSE: N/A** 

	Existing	Parent	Proposed		Existing	Parent	Proposed
	Licensed	Office	Licensed		Licensed	Office	Licensed
	County	County	County		County	County	County
Anderson				Lauderdale			
Bedford				Lawrence			
Benton				Lewis			
Bledsoe				Lincoln			
Blount				Loudon			
Bradley				McMinn			
Campbell				McNairy			
Cannon				Macon			
Carroll				Madison			
Carter				Marion			
Cheatham				Marshall			
Chester				Maury			
Claiborne				Meigs			
Clay				Monroe			
Cocke				Montgomery			
Coffee				Moore			
Crockett				Morgan			
Cumberland				Obion			
Davidson				Overton			
Decatur				Perry			
DeKalb				Pickett			
Dickson				Polk			
Dyer				Putnam			
Fayette				Rhea			
Fentress				Roane			
Franklin				Robertson			
Gibson				Rutherford			
Giles				Scott			
Grainger				Sequatchie			
Greene				Sevier			
Grundy				Shelby			
Hamblen				Smith			
Hamilton				Stewart			
Hancock				Sullivan			
Hardeman				Sumner			
Hardin				Tipton			
Hawkins				Trousdale			
Haywood				Unicoi			
Henderson				Union			
Henry				Van Buren			
Hickman				Warren			
Houston				Washington			
Humphreys				Wayne			
Jackson				Weakley			
Jefferson				White			
Johnson				Williamson			
Knox				Wilson			
Lake							93 911 520

12. Square Footage and Cost Per Square Footage Chart

	age and Cost Per Square Footage			Proposed	Proposed Final Square Footage			
	Existing	Existing	Temporary	Final				
Unit/Department	Location	SF	Location	Location	Renovated	New	Total	
4 <sup>th</sup> Floor, Non-	Nuclear				1			
Invasive Cardiac	Medicine	770	N/A	N/A	770		770	
Department	Rooms							
		7						
					at a	19		
7.2								
			+					
Unit/Department GSF Sub-Total								
Other GSF Total								
Total GSF								
*Total Cost	0.00				\$450,000		\$450,000	
**Cost Per Square Foot					\$584.42		\$584.42	
					□ Below 1 <sup>st</sup> Quartile	☐ Below 1 <sup>st</sup> Quartile	☐ Below 1 <sup>s</sup> Quartile	
	t per Square Fo		_		☐ Between 1 <sup>st</sup> and 2 <sup>nd</sup> Quartile	□ Between 1 <sup>st</sup> and 2 <sup>nd</sup> Quartile	☐ Betweer 1 <sup>st</sup> and 2 <sup>nd</sup> Quartile	
(For quartile	oox on	☐ Between 2 <sup>nd</sup> and 3 <sup>rd</sup> Quartile	☐ Between 2 <sup>nd</sup> and 3 <sup>rd</sup> Quartile	☐ Betweer 2 <sup>nd</sup> and 3 <sup>rd</sup> Quartile				
					■ Above 3 <sup>rd</sup> Quartile	□ Above 3 <sup>rd</sup> Quartile	■ Above 3' Quartile	

<sup>\*</sup> The Total Construction Cost should equal the Construction Cost reported on line A5 of the Project Cost Chart.

<sup>\*\*</sup> Cost per Square Foot is the construction cost divided by the square feet. Please do not include contingency costs.

A. Describe the construction and renovation associated with the proposed provide a description of the existing building, including age of the building and the use of space vacated due to the proposed project.

#### 13. MRI, PET, and/or Linear Accelerator

- 1. Describe the acquisition of any Magnetic Resonance Imaging (MRI) scanner that is adding a MRI scanner in counties with population less than 250,000 or initiation of pediatric MRI in counties with population greater than 250,000 and/or
- 2. Describe the acquisition of any Positron Emission Tomographer (PET) or Linear Accelerator if initiating the service by responding to the following:
- **A.** Complete the chart below for acquired equipment.

Linear Accelerator	Mev Total Cost*: □ New	Types: SRS IMRT IGRT Other By Purchase By Lease Expected Useful Life (yrs) Refurbished If not new, how old? (yrs)
MRI	Tesla: Total Cost*:	Magnet: Breast   Extremity   Open   Short Bore   Other   By Purchase   By Lease   Expected Useful Life (yrs)   Refurbished   If not new, how old? (yrs)
 PET	<ul><li>DET only</li><li>Total Cost*:</li><li>New</li></ul>	■ PET/CT □ PET/MRI ■ By Purchase  \$896,286 □ By Lease Expected Useful Life (yrs) 5 □ Refurbished □ If not new, how old? (yrs)

- B. In the case of equipment purchase, include a quote and/or proposal from an equipment vendor. In the case of equipment lease, provide a draft lease or contract that at least includes the term of the lease and the anticipated lease payments along with the fair market value of the equipment. Response: See Tab 7, Attachment Section A-13-2B.
- **C.** Compare lease cost of the equipment to its fair market value. Note: Per Agency Rule, the higher cost must be identified in the project cost chart.
- **D.** Schedule of Operations:

	Davis of Onesetian	Harris of On auchieus		
Location	Days of Operation	Hours of Operation ( <i>example: 8 am – 3 pm</i> )		
Location	(Sunday through Saturday)			
Fixed Site (Applicant)	Sunday through Saturday	7 am – 11 pm		
Mobile Locations (Applicant)				
(Name of Other Location)		100		
(Name of Other Location)				

<sup>\*</sup> As defined by Agency Rule 0720-9-.01(4)(b)

- **E**. Identify the clinical applications to be provided that apply to the project.
- **F.** If the equipment has been approved by the FDA within the last five years provide documentation of the same. **RESPONSE**: See **TAB 7**, **ATTACHMENT SECTION A-13-2B**.

#### SECTION B: GENERAL CRITERIA FOR CERTIFICATE OF NEED

In accordance with T.C.A. § 68-11-1609(b), "no Certificate of Need shall be granted unless the action proposed in the application for such Certificate is necessary to provide needed health care in the area to be served, can be economically accomplished and maintained, will provide health care that meets appropriate quality standards, and will contribute to the orderly development of health care." In making determinations, the Agency uses as guidelines the goals, objectives, criteria, and standards provided in the State Health Plan.

Additional criteria for review are prescribed in Chapter 11 of the Agency's Rules, Tennessee Rules and Regulations 01730-11.

The following questions are listed according to the four criteria: (1) Need, (2) Economic Feasibility, (3) Quality Standards, and (4) Contribution to the Orderly Development of Health Care. Please respond to each question and provide underlying assumptions, data sources, and methodologies when appropriate.

#### **QUESTIONS**

#### NEED

The responses to this section of the application will help determine whether the project will provide needed health care facilities or services in the area to be served.

1. Provide a response to the applicable criteria and standards for the type of institution or service requested. https://www.tn.gov/hsda/hsda-criteria-and-standards.html

**RESPONSE:** Two sets of criteria and standards are applicable to this project – Positron Emission Tomography Services and Construction, Renovation, Expansion and Replacement of Health Care Institutions. See responses, below.

#### Positron Emission Tomography

1. Applicants proposing a new stationary PET unit should project a minimum of at least 1,000 PET procedures in the first year of service, building to a minimum of 1,600 procedures per year by the second year of service and for every year thereafter. Providers proposing a mobile PET unit should project a minimum of at least 133 mobile PET procedures in the first year of service per day of operation per week, building to an annual minimum of 320 procedures per day of operation per week by the second year of service and for every year thereafter. The minimum number of procedures for a mobile PET unit should not exceed a total of 1,600 procedures per year if the unit is operated more than five (5) days per week. The application for mobile and stationary units should include projections of demographic patterns, including analysis of applicable population-based health status factors and estimated utilization by patient clinical diagnoses category (ICD-9).

For units with a combined utility, e.g., PET/CT units, only scans involving the PET function will count towards the minimum number of procedures.

**RESPONSE**: Based on projected procedures involving the PET function only, STW will exceed the minimum first and second year procedure volumes. These projections are based upon applying the Tennessee statewide PET resident use rate to the projected service area population.

As illustrated in the following table, PET/CT procedures in Tennessee have been growing at nearly 10% per year. As cardiac and cancer incidence rates increase, this growth is projected to increase into the future. Please note that the procedures for all machines includes non-Tennessee residents.

PET/CT Scans in TN by Year

Year	Actual			Projected					
	2015	2016	2017	2018	2019	2020	2021	2022	2023
Proc for all Machines	33,539	36,806	40,313	44,195	48,451	53,117	58,232	63,840	69,988
% Yearly Growth 2015 - 2017			9.63%						
Proc for TN Residents		31,180	33,747	36,524	39,530	42,783	46,304	50,115	54,239
% Yearly Growth 2016 - 2017			8.23%						

Source: Medical Equipment Registry

In sharp contrast, service area resident PET/CT procedures have increased at a mere 3.86% per year, from 9,626 in 2015, to 10,057 in 2016, to 10,384 in 2017. At this rate, all else equal, service area residents can be expected to generate only 13,035 PET/CT procedures.

The actual service area PET/CT resident utilization rate has been lower than the statewide average, reflecting a lack of access to PET/CT services. Therefore, it is reasonable to project that the service area resident utilization rate should mirror that of the Tennessee resident use rate. As illustrated in the following table, achieving the projected Tennessee use rate results in the potential for an additional 9,503 PET/CT procedures in the service area by the 2023 planning horizon.

2023 PET/CT Service Area Projections

Methodology	TN Population	TN Projected PET/CT Proc	TN Use Rate Per 1,000	Service Area Proj Pop	Service Area PET/CT Proc	
TN Use Rate Applied to Service Area Pop	7,045,475	54,239	7.70	2,927,029	22,538	
Historical (2015 - 2017) Procedure Growth Only					13,035	
Underserved PET/CT Procedures					9,503	

Source: Medical Equipment Registry & UTCBER Population Projection Series by TDOH

hospitals captured 46.4% of this market. Allowing for ramp up of the PET/CT service at STW, only 2,100 procedures are projected in 2020 and 2,800 procedures are projected in 2021. Since the STW PET/CT will be operating 24/7, its capacity will exceed the state minimum requirements. Since Saint Thomas Health is projected to capture only a portion of this incremental growth, additional procedures will be available for existing PET/CT providers.

As the flagship of Saint Thomas Health's cardiology service line, this STW project is being undertaken to enhance cardiac nuclear medicine studies and will replace an eleven year old dual SPECT general unit with a cardiac PET/CT. Other alternatives are not clinically appropriate for meeting patient needs.

2. All providers applying for a proposed new PET unit should document that the proposed location is accessible to approximately 75% of the service area's population. Applications that include non-Tennessee counties in their proposed service areas should provide evidence of the number of existing PET units that service the non-Tennessee counties and the impact on PET unit utilization in the non-Tennessee counties, including the specific location of those units located in the non-Tennessee counties, their utilization rates, and their capacity.

**RESPONSE:** As illustrated later in this application, the STW PET/CT service area is based on actual STW inpatient experience. The nine-county primary service area is projected to account for 61.1% of the STW PET/CT procedures. The 28-county secondary service area is projected to account for 26.3% of the STW PET/CT procedures. Thus, over 75% of STW patients are found among these primary and secondary service area counties. Additional inmigration of 12.6% from out-of-area utilization is projected, including possible counties in border states.

3. All providers should document that alternate shared services and lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.

**RESPONSE**: As the flagship of Saint Thomas Health's cardiology service line, this STW project is being undertaken to enhance cardiac nuclear medicine studies and will replace an eleven year old dual SPECT general unit with a cardiac PET/CT. Other alternatives are not clinically appropriate for meeting patient needs.

4. Any provider proposing a new mobile PET unit should demonstrate that it offers or has established referral agreements with providers that offer as a minimum, cancer treatment services, including radiation, medical and surgical oncology services.

RESPONSE: Not applicable.

5. A need likely exists for one additional stationary PET unit in a service area when the combined average utilization of existing PET service providers is at or above 80% of the total capacity of 2,000 procedures during the most recent twelvementh period reflected in the provider medical equipment report maintained by the HSDA. The total capacity per PET unit is based upon the following formula:

Stationary Units: Eight (8) procedures/day x 250 days/year = 2,000 procedures/year

Mobile Units: Eight (8) procedures /day x 50 days/year= 400 procedures/year

The provider should demonstrate that its acquisition of an additional stationary or mobile PET unit in the service area has the means to perform at least 1,000 stationary PET procedures or 133 mobile PET procedures per day of operation per week in the first full one-year period of service operations, and at least 1,600 stationary PET procedures or 320 mobile PET procedures per day of operation per week for every year thereafter.

**RESPONSE**: As illustrated in the table below, the 10.4 existing PET/CT scanner in the service area averaged 1,164 procedures per scanner in 2017. While this is less than the 1,600 procedure minimum, PET/CT utilization has been increasing at nearly 10% per year. At the historical 9.63% annual growth rate, which includes non-resident utilization, the existing PET/CT scanners in the service area are projected to average 2,021 procedures per scanner by the 2023 planning horizon. Even including the recently approved PET/CT scanner for Lebanon PET Scan Center and this proposed STW PET/CT scanner, 2023 PET/CT utilization is projected to average 1,695 procedures per scanner. This exceeds the 80% minimum requirement.

Service Area PET/CT Utilization

		Facility		2023			
County	Provider Type		# of Machines	Numeric # of Machines	Procedures	Projections 9.63% CAGR	Utilization at
Coffee	HOSP	Tennova healthcare - Harton	1 - 2/month	0.1	22	38	23.8%
Davidson	ODC	Imaging Alliance - Nashville PET, LLC	1	1	1,306	2,267	141.7%
Davidson	ODC	Premier Radiology Midtown	1	1	762	1,323	82.7%
Davidson	PO	Tennessee Oncology, PET Services	1	1	1,244	2,160	135.0%
Davidson	HOSP	TriStar Centennial Medical Center	1	1	974	1,691	105.7%
Davidson	HOSP	Vanderbilt Medical Center	2	2	3,313	5,752	179.8%
Maury	HO5P	Maury Regional Medical Center	1-2/week	0.4	691	1,200	187.5%
Montgom	HOSP	Tennova Healthcare - Clarksville	1-1/week	0.2	316	549	171.6%
Putnam	HOSP	Cookeville Regional Medical Center	1	1	708	1,229	76.8%
Robertsor	HOSP	Northcrest Medical Center	1-1/week	0.2	137	238	74.4%
Rutherfor	ODC	Tennessee PET Scan Center	1	1	2,126	3,691	230.7%
Sumner	H-Imaging	Diagnostic Center at Sumner Station	1	1	331	575	35.9%
Williamso	HOSP	Williamson Medical Center	1 -half/week	0.5	178	309	38.6%
				10.4	12,108	21,022	126.3%

Note: Additional PET/CT scanner approved at Lebanon PET Scan Center, CN1905-018

Source: Medical Equipment Registry

- 6. The applicant should provide evidence that the PET unit is safe and effective for its proposed use.
  - a. The United States Food and Drug Administration (FDA) must certify the proposed PET unit for clinical use.

b. The applicant should demonstrate that the proposed PET procedures will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.

**RESPONSE**: Please refer to the architect's certification letter at TAB 9.

c. The applicant should demonstrate how emergencies within the PET unit facility will be managed in conformity with accepted medical practice.

**RESPONSE**: As a hospital-based PET/CT services, any emergency can and will be appropriately managed within the STW facility.

d. The applicant should establish protocols that assure that all clinical PET procedures performed are medically necessary and will not unnecessarily duplicate other services.

<u>RESPONSE</u>: STW's cardiac PET/CT service will adhere to the quality and utilization protocols currently in place at STW. Please refer to the policies at **TAB 15**. Rather than duplicating services, the proposed cardiac PET/CT will replace an eleven year old dual SPECT general unit.

e. The PET unit should be under the medical direction of a licensed physician. The applicant should provide documentation that attests to the nature and scope of the duties and responsibilities of the physician medical director. Clinical supervision and interpretation services must be provided by physicians who are licensed to practice medicine in the state of Tennessee and are board certified in Nuclear Medicine or Diagnostic Radiology. Licensure and oversight for the handling of medical isotopes and radiopharmaceuticals by the Tennessee Board of Pharmacy and/or the Tennessee Board of Medical Examiners-whichever is appropriate given the setting-is required. Those qualified physicians that provide interpretation services should have additional documented experience and training, credentialing, and/or board certification in the appropriate specialty and in the use and interpretation of PET procedures.

**RESPONSE**: STW has existing nuclear imaging capabilities and will draw upon the physician leadership of Dante J. Graves, MD. Please refer to Dr. Graves' qualifications at **TAB 19**.

f. All applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. An applicant's arrangements with its physician medical director must specify that said physician be an active member of the subject transfer agreement hospital medical staff.

**RESPONSE:** As a hospital-based PET/CT services, any emergency can and will be appropriately managed within the STW facility. Dante J. Graves, MD is an active member of the STW medical staff.

7. The applicant should provide assurances that it will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.

<u>RESPONSE</u>: STW will submit required data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.

- 8. In light of Rule 0720-4-.01(1), which lists the factors concerning need on which an application may be evaluated, the HSDA may decide to give special consideration to an applicant:
  - a. Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;

**RESPONSE**: This application qualifies for special consideration under this criterion. All but three of the 37 PET/CT service area counties are designated by the United States Health Resources and Services Administration as a medically underserved area. Please refer to the documentation in **TAB 20**.

 b. Who documents that the service area population experiences a prevalence, incidence and/or mortality from cancer, heart disease, neurological impairment or other clinical conditions applicable to PET unit services that is substantially higher than the State of Tennessee average;

**RESPONSE:** This application qualifies for special consideration under this criterion. According to TDOH, diseases of the heart are the leading cause of death in Tennessee. Data indicate that cardiac mortality increased 8.1% from 2012 to 2017. Twenty-five service area counties (68% of the total) have cardiac death rates greater than the Tennessee rate, with six exceeding the Tennessee rate by more than 150% and another two by more than 200%. Please refer to the documentation in **TAB 21**.

c. Who is a "safety net hospital" or a "children's hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program and/or is a comprehensive cancer diagnosis and treatment program as designated by the Tennessee Department of Health and/or the Tennessee Comprehensive Cancer Control Coalition; or

RESPONSE: Not applicable.

d. Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program.

**RESPONSE**: This application qualifies for special consideration under this criterion. STW already contracts with all the TennCare MCOs in its area and participates in the Medicare program.

# Construction, Renovation, Expansion and Replacement of Health Care Institutions

1. Any project that includes the addition of beds, services, or medical equipment will be reviewed under the standards for those specific activities.

**RESPONSE**: The standards for medical equipment (PET/CT) are addressed immediately above. In addition to projected numeric need, the STW cardiac PET/CT project meets the requirements for special consideration due to: (1) offering services in a medically underserved area (2) to a service area population experiencing heart disease mortality that is substantially higher than the State of Tennessee average and (3) contracts with at least one TennCare MCO while also participating in the Medicare program.

- 2. For relocation or replacement of an existing licensed health care institution:
  - a. The applicant should provide plans which include costs for both renovation and relocation, demonstrating the strengths and weaknesses of each alternative.
  - b. The applicant should demonstrate that there is an acceptable existing or projected future demand for the proposed project.

**RESPONSE**: Not applicable. The proposed STW cardiac PET/CT project will be added to the existing STW facility.

- 3. For renovation or expansions of an existing licensed health care institution:
  - a. The applicant should demonstrate that there is an acceptable existing demand for the proposed project.

**RESPONSE**: The standards for medical equipment (PET/CT) are addressed immediately above. In addition to projected numeric need, the STW cardiac PET/CT project meets the requirements for special consideration due to: (1) offering services in a medically underserved area (2) to a service area population experiencing heart disease mortality that is substantially higher than the State of Tennessee average and (3) contracts with at least one TennCare MCO while also participating in the Medicare program.

b. The applicant should demonstrate that the existing physical plant's condition warrants major renovation or expansion

<u>RESPONSE</u>: Not applicable. The 770 square feet of renovation is for equipment installation only.

2. Describe how this project relates to existing facilities or services operated by the applicant including previously approved Certificate of Need projects and future long-range development plans.

**RESPONSE:** The initiation of cardiac/PET CT services and the purchase of a cardiac PET/CT scanner at STW is an essential component in the continuum of advanced cardiac services at Saint Thomas Health.

• Saint Thomas Heart became Tennessee's first heart transplant program in 1985.

- The Aortic Center is also located on the West hospital campus.
- Cardiopulmonary Rehab services are located at West, Rutherford and River Park.
- Chest Pain clinics are located at West, Midtown, Rutherford, River Park, Hickman, DeKalb, Stones River and Highlands.
- Research and Clinical Trials are underway in cardiac intervention (4), electrophysiology (2) and cardiac surgery (4).
- 3. Identify the proposed service area and provide justification for its reasonableness. Submit a county level map for the Tennessee portion of the service area using the map on the following page, clearly marked and shaded to reflect the service area as it relates to meeting the requirements for CON criteria and standards that may apply to the project. Please include a discussion of the inclusion of counties in the border states, if applicable. Attachment Section B Need-3.

Complete the following utilization tables for each county in the service area, if applicable:

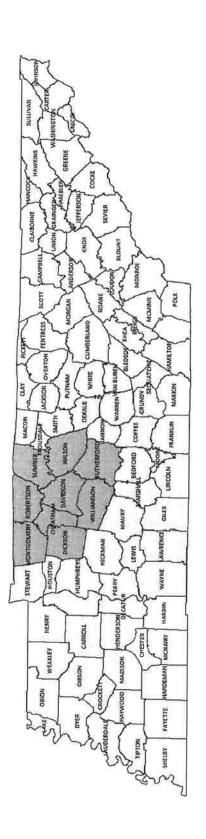
<u>Response</u>: The nine-county primary service area is projected to account for 61.1% of the STW PET/CT procedures. The 28-county secondary service area is projected to account for 26.3% of the STW PET/CT procedures. Additional in-migration of 12.6% from out-of-area utilization is projected, including possible counties in border states.

Please refer to the following two tables.

Service Area Counties	Historical Utilization-County Residents - Most Recent Year (YEAR = 2018 ) (STW Inpatients from JAR)	% of total □ procedures □ cases ■ patients □ Other
Davidson	6,270	32.0%
Williamson	1,276	6.5%
Rutherford	841	4.3%
Cheatham	778	4.0%
Montgomery	763	3.9%
Dickson	603	3.1%
Sumner	587	3.0%
Wilson	587	3.0%
Warren	458	2.3%
Hickman	392	2.0%
Coffee	378	1.9%
Henry	364	1.9%
Lincoln	300	1.5%
Giles	276	1.4%
Humphreys	256	1.3%
Robertson	253	1.3%
Lawrence	244	1.2%
Benton	234	1.2%
Maury	225	1.2%
Bedford	219	1.1%
Franklin	197	1.0%
Putnam	197	1.0%
Marshall	192	1.0%
Macon	145	0.7%
DeKalb	144	0.7%
Stewart	134	0.7%
Smith	124	0.6%
White	123	0.6%
Carroll	112	0.6%
Decatur	104	0.5%
Perry	94	0.5%
Cannon	88	0.5%
Houston	87	0.4%
Wayne	80	0.4%
Lewis	40	0.4%
Trousdale	29	0.2%
Moore	9	0.1%
Service Area	<u> </u>	0.1%
Subtotal	17,203	87.7%
Other	2,412	12.3%
Total	19,615	100.0%

Service Area Counties	Projected Utilization-County Residents- Year 1 (YEAR = 2020 ) (STW 2,100 PET/CT Procedures	% of total ■ procedures □ cases □ patients □ Other
Davidson	671	32.0%
Williamson	137	6.5%
Rutherford	90	4.3%
Cheatham	83	4.0%
Montgomery	82	3.9%
Dickson	64	3.1%
Sumner	63	3.0%
Wilson	63	3.0%
Warren	49	2.3%
Hickman	42	2.0%
Coffee	41	1.9%
Henry	39	1.9%
Lincoln	32	1.5%
Giles	30	1.4%
Humphreys	28	1.3%
Robertson	27	1.3%
Lawrence	26	1.2%
Benton	25	1.2%
Maury	24	1.2%
Bedford	24	1.1%
Franklin	21	1.0%
Putnam	21	1.0%
Marshall	21	1.0%
Macon	16	0.7%
DeKalb	15	0.7%
Stewart	14	0.7%
Smith	13	0.6%
White	13	0.6%
Carroll	12	0.6%
Decatur	11	0.5%
Perry	10	0.5%
Cannon	9	0.5%
Houston	9	0.4%
Wayne	9	0.4%
Lewis	4	0.2%
Trousdale	3	0.1%
Moore	1	0.1%
Service Area		
Subtotal	1,842	87.7%
Outside Service Area	258	12.3%
Total	2,100	100%

County Level Map



- **4. A**. 1) Describe the demographics of the population to be served by the proposal.
  - 2) Provide the following data for each county in the service area using current and projected population data from the Department of Health

(https://www.tn.gov/content/tn/health/health-program-areas/statistics/health-data/con.html

), the most recent enrollee data from the Division of TennCare

(https://www.tn.gov/tenncare/information-statistics/enrollment-data.html ), and US

Census Bureau demographic information (:

http://factfinder.census.gov/faces/nav/jsf/pages/index.xhtml ),.

TennCare Enrollment Data: https://www.tn.gov/tenncare/information-statistics/enrollment-data.html

Census Bureau Fact Finder: http://factfinder.census.gov/faces/nav/jsf/pages/index.xhtml

		Depa	artmen	t of H	ealth/	Health St	atistics			Censu	ıs Bur	eau	Ten	nCare
Demographic Variable/Geographic Area	Total Population- Current Year	Total Population- Projected Year	Total Population-% Change	*Target Population-	Current Year	Target Population- Project Year	Target Population- % Change	Target Population Projected Year as % of Total	Median Age	Median Household Income	Person Below Poverty Level	Person Below Poverty Level as % of Total	TennCare Enrollees	TennCare Enrollees ss % of Total
County A														
County B, etc.														
Service Area Total														
State of TN Total														

<sup>\*</sup> Target Population is population that project will primarily serve. For example, nursing home, home health agency, hospice agency projects typically primarily serve the Age 65+ population; projects for child and adolescent psychiatric services will serve the Population Ages 0-17. Projected Year is defined in select service-specific criteria and standards. If Projected Year is not defined, default should be four years from current year, e.g., if Current Year is 2019, then default Projected Year is 2023.

Be sure to identify the target population, e.g., Age 65+, the current year and projected year being used.

RESPONSE: See TAB 8, ATTACHMENT SECTION B-4A.

**B.** Describe the special needs of the service area population, including health disparities, the accessibility to consumers, particularly the elderly, women, racial and ethnic minorities, TennCare or Medicaid recipients, and low-income groups. Document how the business plans of the facility will take into consideration the special needs of the service area population.

**RESPONSE**: STW provides care to all patients regardless of sex, race, ethnicity or income. It also provides care to uninsured and low-income populations as well as TennCare patients.

In Tennessee, Ascension's Saint Thomas Health operates nine hospitals in addition to a comprehensive network of affiliated joint ventures, medical practices, clinics and rehabilitation facilities that cover a 68-county area and employ more than 8,000 associates. Across the state, Saint Thomas Health provided more than \$100 million in community

benefit and care of persons living in poverty in fiscal year 2018. Serving Tennessee for 15 years, Ascension is a faith-based healthcare organization committed to delivering compassionate, personalized care to all, with special attention to persons living in poverty and those most vulnerable. Ascension is one of the largest non-profit health systems in the U.S. as well as one of the world's largest Catholic health system, operating 2,500 sites of care – including 141 hospitals and more than 30 senior living facilities – in 24 states and the District of Columbia.

5. Describe the existing and approved but unimplemented services of similar healthcare providers in the service area. Include utilization and/or occupancy trends for each of the most recent three years of data available for this type of project. List each provider and its utilization and/or occupancy individually. Inpatient bed projects must include the following data: Admissions or discharges, patient days, average length of stay, and occupancy. Other projects should use the most appropriate measures, e.g., cases, procedures, visits, admissions, etc. This doesn't apply to projects that are solely relocating a service.

**RESPONSE:** The 10.4 existing PET/CT scanner in the service area averaged 1,164 procedures per scanner in 2017. As documented previously, this is less than the 1,600 procedure minimum but PET/CT utilization has been increasing at nearly 10% per year. At the historical 9.63% annual growth rate, which includes non-resident utilization, the existing PET/CT scanners in the service area are projected to average 2,021 procedures per scanner by the 2023 planning horizon. Even including the recently approved PET/CT scanner for Lebanon PET Scan Center and this proposed STW PET/CT scanner, 2023 PET/CT utilization is projected to average 1,695 procedures per scanner. This exceeds the 80% minimum requirement.

Service	Area	PET/CT	Utilization

			2017	20	15	2	016	20	17
County	Provider Type	Provider Type Facility	Numeric# of Machines	Procedures	Utilization at 1,600	Procedures	Utilization at 1,600	Procedures	Utilization a
Coffee	HOSP	Tennova healthcare - Harton	0.1	38	23.8%	46	28.8%	22	13.8%
Davidson	ODC	Imaging Alliance - Nashville PET, LLC	1	1,324	82.8%	1,155	72.2%	1,306	81.6%
Davidson	opc	Premier Rediology Midtown	1	477	29.8%	608	38.0%	762	47.6%
Davidson	PO	Tennessee Oncology, PET Services	1	1,220	76.3%	1,218	76.1%	1,244	77.8%
Davidson	HOSP	TriStar Centennial Medical Center	1	526	32.9%	765	47.8%	974	60.9%
Davidson	HOSP	Vanderbilt Medical Center	2	3,535	110.5%	3,852	120.4%	3.313	103.5%
Maury	HOSP	Maury Regional Medical Center	0.4	508	79.4%	604	94.4%	691	108.0%
Montgome	HOSP	Tennova Healthcare - Clarksville	0.2	311	97.2%	334	104.4%	316	98.8%
Putnam	HOSP	Cookeville Regional Medical Center	1	605	37.8%	656	41.0%	708	44.3%
Robertson	HOSP	Northcrest Medical Center	0.2	23	7.2%	174	54.4%	137	42.8%
Rutherford	ODC	Tennessee PET Scan Center	1	1,628	101.8%	1,932	120.8%	2,126	132.9%
Sumner	H-Imaging	Diagnostic Center at Sumner Station	1	0	0.0%	265	16.5%	331	20.7%
Williamsor	HOSP	Williamson Medical Center	0.5	130	16.3%	164	20.5%	178	22.3%
			10,4	10,325	62.0%	11,773	70.8%	12.108	72.8%

Note: Additional PET/CT scanner approved at Lebanon PET Scan Center, CN1905-018

Unity Medical Center (Coffee County) stopped service in 2016 Source: Medical Equipment Registry

6. Provide applicable utilization and/or occupancy statistics for your institution services for each of the past three years and the projected annual utilization for each of the two years following completion of the project. Additionally, provide the details regarding the methodology used to project utilization. The methodology <u>must include</u> detailed calculations or documentation from referral sources, and identification of all assumptions.

**RESPONSE:** As a new service, historical cardiac PET/CT data is not available. Projections are provided in the PET criteria and standards section of this application.

#### **ECONOMIC FEASIBILITY**

The responses to this section of the application will help determine whether the project can be economically accomplished and maintained.

- 1. Project Cost Chart Instructions
  - **A.** All projects should have a project cost of at least \$15,000 (the minimum CON Filing Fee) (See Application Instructions for Filing Fee)

**RESPONSE:** The applicant acknowledges that the filing fee shall be an amount equal to \$5.75 per \$1,000 of the estimated project cost involved, but in no case shall the fee be less than \$15,000 or more than \$95,000. At an estimated project cost of \$1,625,673 (Project Cost Form, line D), the calculated filing fee would be \$15,000, the minimum filing fee. Please find a check of this amount made payable to the Health Services and Development Agency.

**B.** The cost of any lease (building, land, and/or equipment) should be based on fair market value or the total amount of the lease payments over the initial term of the lease, whichever is greater. Note: This applies to all equipment leases including by procedure or "per click" arrangements. The methodology used to determine the total lease cost for a "per click" arrangement must include, at a minimum, the projected procedures, the "per click" rate and the term of the lease.

**RESPONSE:** Not applicable. This project does not involve any leases.

**C.** The cost for fixed and moveable equipment includes, but is not necessarily limited to, maintenance agreements covering the expected useful life of the equipment; federal, state, and local taxes and other government assessments; and installation charges, excluding capital expenditures for physical plant renovation or in-wall shielding, which should be included under construction costs or incorporated in a facility lease.

**RESPONSE:** Reported equipment costs are consistent with these guidelines.

**D.** The Total Construction Cost reported on line 5 should equal the Total Cost reported on the Square Footage Chart.

**RESPONSE:** Minor renovation is involved in the proposed project.

- **E.** For projects that include new construction, modification, and/or renovation— **documentation must be** provided from a licensed architect or construction professional that support the estimated construction costs. Provide a letter that includes the following:
  - 1) A general description of the project:
  - 2) An estimate of the cost to construct the project;
  - 3) A description of the status of the site's suitability for the proposed project; and
  - 4) Attesting the physical environment will conform to applicable federal standards, manufacturer's specifications and licensing agencies' requirements including the AIA

Guidelines for Design and Construction of Hospital and Health Care Facilities or comparable document in current use by the licensing authority.

RESPONSE: See TAB 9, Attachment Section B-Economic-1E.

#### PROJECT COST CHART

Construction and equipment acquired by purchase: 1. Architectural and Engineering Fees \_\$\_\_\_\_ 49,000 2. Legal, Administrative (Excluding CON Filing Fee), 87,559 Consultant Fees 3. Acquisition of Site 4. Preparation of Site 5. **Total Construction Costs** 450,000 6. Contingency Fund 126,828 7. Fixed Equipment (Not included in Construction Contract) 896,286 8. Moveable Equipment (List all equipment over \$50,000 as separate attachments) Other (Specify) Furnishings, IT 9. 16,000 B. Acquisition by gift, donation, or lease: 1. Facility (inclusive of building and land) 2. **Building only** 3. Land only Equipment (Specify) 4. 5. Other (Specify) C. Financing Costs and Fees: 1. Interim Financing 2. **Underwriting Costs** 3. Reserve for One Year's Debt Service 4. Other (Specify) D. **Estimated Project Cost** 1,625,673 (A+B+C) E :: **CON Filing Fee** 15,000  $\mathsf{F}_{\mathsf{s}}$ **Total Estimated Project Cost** TOTAL (D+E) \$ 1,640,673

27

2. Identify the funding source(s) for this project.

Check the applicable item(s) below and briefly summarize how the project will be financed. (Documentation for the type of funding MUST be inserted at the end of the application, in the correct alpha/numeric order and identified as Attachment Section B-Economic Feasibility-2.)

- A. Commercial loan Letter from lending institution or guarantor stating favorable initial contact, proposed loan amount, expected interest rates, anticipated term of the loan, and any restrictions or conditions;
- B. Tax-exempt bonds Copy of preliminary resolution or a letter from the issuing authority stating favorable initial contact and a conditional agreement from an underwriter or investment banker to proceed with the issuance;
- C. General obligation bonds Copy of resolution from issuing authority or minutes from the appropriate meeting;
- \_\_\_ D. Grants Notification of intent form for grant application or notice of grant award;
- X E. Cash Reserves Appropriate documentation from Chief Financial Officer of the organization providing the funding for the project and audited financial statements of the organization; and/or
- F. Other Identify and document funding from all other sources.

RESPONSE: See TAB 10, Attachment Section B-Economic-2.

3. Complete Historical Data Charts on the following two pages—<u>Do not modify the Charts</u> provided or submit Chart substitutions!

Historical Data Chart(s) provide revenue and expense information for the last *three (3)* years for which complete data is available. The "Project Only Chart" provides information for the services being presented in the proposed project while the "Total Facility Chart" provides information for the entire facility. Complete both, if applicable.

Note that "Management Fees to Affiliates" should include management fees paid by agreement to the parent company, another subsidiary of the parent company, or a third party with common ownership as the applicant entity. "Management Fees to Non-Affiliates" should include any management fees paid by agreement to third party entities not having common ownership with the applicant.

**RESPONSE:** Not applicable. As a new service, historical cardiac PET/CT data is not available.

# Supplemental #1 September 30, 2019 9:29 A.M.

□ Project Only■ Total Facility

# HISTORICAL DATA CHART

Give information for the last *three (3)* years for which complete data are available for the facility or agency. The fiscal year begins in <u>July</u> (Month). (Dollars in Thousands)

begi	ns in <sub>.</sub>	July (Month). (Dollars in Thousands)	Voor 2017	<b>Voor</b> 2018	Voor 2010
			Year 2017	Year_2018	Year_2019
A.		zation Data	00.050	20,000	27.202
Б	-	cify Unit of Measure <u>Equivalent Discharges</u>	28,658	28,998	27,302
B.		enue from Services to Patients	¢ 1 262 E04	£1 402 004	¢1 456 570
	1.	Inpatient Services	\$ 1,262,504	\$ <u>1,402,091</u>	\$ <u>1,456,572</u>
	2.	Outpatient Services	656,721	_702,570	<u>763,335</u>
	3. 4.	Emergency Services Other Operating Revenue (Specify) Suppl Care Program,		3-	-
	4.	Cafeteria/Vending, Income from Unconsold Entities, Misc.	24,911	23,900	26,559
		Gross Operating Revenue	\$ <u>1,944,136</u>	\$2,128,561	\$2,246,466
C.	Ded	uctions from Gross Operating Revenue			
	1.	Contractual Adjustments	\$1,424,102	\$ <u>1,578,198</u>	\$ <u>1,673,456</u>
	2.	Provision for Charity Care	58,413	73,887	75,748
	3.	Provisions for Bad Debt	17,578	11,700	22,633
		Total Deductions	_	\$1,663,785	\$ <u>1,771,837</u>
NET	OPE	RATING REVENUE		· vitavicie in elet	
			\$_444,043	\$_464,776	\$_474,629
D.		rating Expenses			
	1.	Salaries and Wages	70.405	04.000	0.5.000
		a. Direct Patient Care	79,465	84,003	<u>85,026</u>
	0	b. Non-Patient Care	34,056	<u> 36,001</u>	36,440
	2.	Physician's Salaries and Wages	05 E10	00.007	102 542
	3. 4.	Supplies Rent	95,519	99,087	103,543
	4.	a. Paid to Affiliates			
		b. Paid to Non-Affiliates			-
	5.	Management Fees:	- 4	4-14-14-14-14-14-14-14-14-14-14-14-14-14	
	٥.	a. Paid to Affiliates			
		b. Paid to Non-Affiliates			-
	6.	Other Operating Expenses (D6)	156,263	158,145	163,479
		Total Operating Expenses	\$ <u>365,303</u>	\$ <u>377,236</u>	\$ 388,488
E.	Earr	nings Before Interest, Taxes and Depreciation	\$78,740	\$ 87,540	\$ <u>86,141</u>
F.	Non-	Operating Expenses			
	1.	Taxes	\$ <u>16,044</u>	\$16,044	\$ <u>16,010</u>
	2.	Depreciation	18,584	18,775	18,850
	3.	Interest	3,370	3,537	3,656
	4.	Other Non-Operating Expenses			
		Total Non-Operating Expenses	\$37,998	\$38,356	\$ <u>38,516</u>
NET	INCC	ME (LOSS)	\$_40,742	\$_49,184	\$_47,625

Chart Continues Onto Next Page

	51			-	tember 30, 2019
NET	INCO	ME (LOSS)	\$40,742	\$_49, <b>18</b> ;29	A <sub>\$</sub> M. <sub>47,625</sub>
G.	Othe	r Deductions			
	1.	Annual Principal Debt Repayment	\$	\$	\$
	2.	Annual Capital Expenditure	5 <del></del>		-
			Total Other Deductions \$	\$	\$
			NET BALANCE \$_40,742	\$49,184	\$ <u>47,625</u>
			DEPRECIATION \$ 18,584	\$ <u>18,775</u>	\$18,850
		FREE CASH FLOW (Net	Balance + Depreciation) \$ 59,326	\$ 67,959	\$ <u>66,475</u>

☐ Project Facility

■ Total Only

# HISTORICAL DATA CHART-OTHER EXPENSES

OTHER OPERATING EXPEN	ISES CATEGORIES	Year <u>2017</u>	Year <u>2018</u>	Year <u>2019</u>
Purchased Services		\$132,385	\$91,187	\$44,059
<ol><li>Professional Fees</li></ol>		8,217	8,569	9,404
3. Insurance		2,658	2,708	2,530
4. Miscellaneous		13,003	<u>55,681</u>	107,486
5				
6		in the state of th		
7				
*Total Other Expenses		\$ <u>156,263</u>	\$ <u>158,145</u>	\$ <u>163,479</u>

<sup>\*</sup>Total other expenses should equal Line D.6. In the Historical Data Chart

4. Complete Projected Data Charts on the following two pages – <u>Do not modify the Charts</u> provided or submit Chart substitutions!

Projected Data Chart(s) provide information for the two years following the completion of the project. The "Project Only Chart" should reflect revenue and expense projections for the project (*i.e.*, if the application is for additional beds, include anticipated revenue from the proposed beds only, not from all beds in the facility). The "Total Facility Chart" should reflect information for the total facility. Complete both, if applicable.

Note that "Management Fees to Affiliates" should include management fees paid by agreement to the parent company, another subsidiary of the parent company, or a third party with common ownership as the applicant entity. "Management Fees to Non-Affiliates" should include any management fees paid by agreement to third party entities not having common ownership with the applicant.

**RESPONSE:** Please refer to the completed projected data chart for the proposed PET/CT program at STW on the following pages.

9:29 And ect Only

□ Total Facility

#### PROJECTED DATA CHART

Give information for the two (2) years following the completion of this proposal. The fiscal year begins in <u>October</u> (Month).

(Mo	nth).	Year_2020_	Year_2021
A.	Utilization Data		
	Specify Unit of Measure Procedures	2,100	2,800
B.	Revenue from Services to Patients		
	Inpatient Services	\$	\$
	2. Outpatient Services	14,787,601	19,716,801
	Emergency Services		
	Other Operating Revenue (Specify)	<u> </u>	-
		ting Revenue \$ <u>14,787,601</u>	\$ <u>19,716,801</u>
С	Deductions from Gross Operating Revenue		
8			
	Contractual Adjustments	\$ <u>10,351,321</u>	\$ <u>14,196,097</u>
	2. Provision for Charity Care	295,752	394,336
	3. Provisions for Bad Debt	1,330,884	1,774,512
NET	OPERATING REVENUE	al Deductions \$ 11,977,957	\$ <u>16,364,945</u>
D.	Operating Expenses	\$ 2,809,644	\$ <u>3,351,856</u>
υ.	Salaries and Wages		
	a. Direct Patient Care	442,968	454.042
	b. Non-Patient Care	442,908	454,042
	Physician's Salaries and Wages	1	
	Supplies	495,847	495,847
	4. Rent	433,047	495,64 <i>1</i> _
	a. Paid to Affiliates		
	b. Paid to Non-Affiliates		~
	5. Management Fees:	S <del></del>	
	a. Paid to Affiliates		
	b. Paid to Non-Affiliates	-	
	6. Other Operating Expenses (D6)	167,484	167,484
	Total Operat	ing Expenses \$ 1,106,299	\$ 1,117,373
E.	Earnings Before Interest, Taxes and Depreciation	\$ 1,703,345	\$2,234,483
ь. F.		ψ <u>1,700,040</u>	Ψ
г.	Non-Operating Expenses  1. Taxes	\$	\$
	2. Depreciation	193,333	193,333
	3. Interest		
	4. Other Non-Operating Expenses	-	
	Total Non-Operat	ing Expenses \$193,333	\$193,333
NET	INCOME (LOSS)	\$1,510,012	\$ 2,041,150
		Ψ	210111100

Chart Continues Onto Next Page

		54		Supplemental #1 September 30, 2019
NET	INCO	ME (LOSS)	\$ <u>1,510,012</u>	9:29 A:M1.150
Э.	1.	Deductions Estimated Annual Principal Debt Repayment Annual Capital Expenditure	\$	\$
		Total Other Deductions	\$ \$	\$
		NET BALANCE	\$ <u>1,510,012</u>	\$ 2,041,150
		DEPRECIATION	\$ <u>193,333</u>	\$ <u>193,333</u>
		FREE CASH FLOW (Net Balance + Depreciation)	\$ <u>1,703,345</u>	\$2,234,483

Project Facility

☐ Total Only

# **PROJECTED DATA CHART-OTHER EXPENSES**

OTHER OPERATING EXPENSES CATEGORIES	Year 2020	Year 2021	
(D6)			
1. Purchased Services	\$100,000	\$100,000	
2. Miscellaneous	67,484	67,484	
3.		41	
4.	S		
5	=		
6.			
7.		-	
*Total Other Expenses	5 167,484	\$ 167,484	

<sup>\*</sup>Total other expenses should equal Line D.6. In the Projected Data Chart

# Supplemental #2 September 30, 2019 4:24 Project Only Total Facility

#### PROJECTED DATA CHART

Give information for the two (2) years following the completion of this proposal. The fiscal year begins in <u>July</u> (Month). (Dollar in Thousands)

(	(	Year_2020_	Year_2021_
A.	Utilization Data		
	Specify Unit of Measure <u>Equivalent Discharges</u>	<u>27,225</u>	27,270
B.	Revenue from Services to Patients		
	Inpatient Services	\$ <u>1,571,132</u>	\$ <u>1,648,363</u>
	2. Outpatient Services	798,884	838,154
	3. Emergency Services		,
	<ol> <li>Other Operating Revenue (Specify) <u>Suppl Care Program.</u></li> </ol>		
	Cafeteria/Vending, Income from Unconsold Entities, Misc.	22,751	23,949
	Gross Operating Reve	nue \$ <u>2,392,767</u>	\$ <u>2,510,466</u>
С	Deductions from Gross Operating Revenue		
(5 <b>6</b> ):	Contractual Adjustments	\$ <u>1,807,470</u>	\$_1,909,062
	Provision for Charity Care	77,118	81,453
	Provisions for Bad Debt	23,859	24,531
	Total Deducti	A CONTRACTOR OF THE PARTY OF TH	\$ 2,015,046
NET	Γ OPERATING REVENUE	\$ 484,320	\$ 495,420
D.	Operating Expenses	<del></del>	
	1. Salaries and Wages	-	
	a. Direct Patient Care	86,624	88,978
	b. Non-Patient Care	37,125	38,134
	2. Physician's Salaries and Wages		
	3. Supplies	103,935	105,494
	4. Rent		
	a. Paid to Affiliates		
	b. Paid to Non-Affiliates		
	5. Management Fees:		
	a. Paid to Affiliates	-	
	b. Paid to Non-Affiliates	\$ <u></u>	
	6. Other Operating Expenses (D6)	172,524	177,045
	Total Operating Exper	ses \$ 400,208	\$409,651
E.	Earnings Before Interest, Taxes and Depreciation	\$ 84,112	\$85,769
F.	Non-Operating Expenses		
	1. Taxes	\$ <u>16,044</u>	\$ <u>16,044</u>
	2. Depreciation	21,056	21,000
	3. Interest	3,635	3,668
	4. Other Non-Operating Expenses		
	Total Non-Operating Expen	ses \$ 40,735	\$40,712
NET	INCOME (LOSS)	\$43,377	\$ 45,057

Chart Continues Onto Next Page

	56		Supplemental #2 September 30, 2019
INCO	ME (LOSS)	\$43,377	4:24 P.M <sub>5,057</sub>
Othe	r Deductions		
1.	Estimated Annual Principal Debt Repayment	\$	\$
2.	Annual Capital Expenditure	-	
	Total Other Deductions	\$	\$
	NET BALANCE	\$ 43,377	\$45,057
	DEPRECIATION	\$21,056	\$21,000
	FREE CASH FLOW (Net Balance + Depreciation)	\$64,433	\$66,057
	Othe 1.	Other Deductions  1. Estimated Annual Principal Debt Repayment  2. Annual Capital Expenditure  Total Other Deductions  NET BALANCE  DEPRECIATION	Other Deductions  1. Estimated Annual Principal Debt Repayment  2. Annual Capital Expenditure  Total Other Deductions  NET BALANCE  43,377  DEPRECIATION  21,056

□ Project Facility

■ Total Only

# PROJECTED DATA CHART-OTHER EXPENSES

Year <u>2020</u>	Year <u>2021</u>
\$ <u>43,313</u>	\$44,828
8,841	9,501
2,461	<u>2,514</u>
117,909	120,202
÷	
: <del></del>	3
\$ <u>172,524</u>	\$ <u>177,045</u>
	\$43,313 8,841 2,461 117,909

<sup>\*</sup>Total other expenses should equal Line D.6. In the Projected Data Chart

**5. A.** Please identify the project's average gross charge, average deduction from operating revenue, and average net charge using information from the Projected Data Charts for Year 1 and Year 2 of the proposed project. Complete Project Only Chart and Total Facility Chart, if applicable.

Project Only Chart

	Previous Year to Most Recent Year Year	Most Recent Year Year	Year One Year <u>2020</u>	Year Two Year <u>2021</u>	% Change (Current Year to Year 2)
Gross Charge (Gross Operating Revenue/Utilization Data)	N/A	N/A	\$7,042	\$7,042	N/A
Deduction from Revenue (Total Deductions/Utilization Data)	N/A	N/A	\$5,704	\$5,845	N/A
Average Net Charge (Net Operating Revenue/Utilization Data)	N/A	N/A	\$1,338	\$1,197	N/A

**Total Facility Chart** 

	Previous Year to Most Recent Year Year <u>2018</u>	Most Recent Year Year <u>2019</u>	Year One Year <u>2020</u>	Year Two Year <u>2021</u>	% Change (Current Year to Year 2)
Gross Charge (Gross Operating Revenue/Utilization Data)	\$73,404	\$82,282	\$87,889	\$92,060	11.9%
Deduction from Revenue (Total Deductions/Utilization Data)	\$57,376	\$64,898	\$70,099	\$73,892	13.9%
Average Net Charge (Net Operating Revenue/Utilization Data)	\$16,028	\$17,384	\$17,790	\$18,168	4.5%

**B.** Provide the proposed charges for the project and discuss any adjustment to current charges that will result from the implementation of the proposal. Additionally, describe the anticipated revenue from the project and the impact on existing patient charges.

**RESPONSE:** As indicated in the table above, the PET/CT scanner is a new service at STW. Gross charges are not expected to increase during the first five years. The PET/CT service is expected to be profitable in its first year of operation.

C. Compare the proposed charges to those of similar facilities/services in the service area/adjoining service areas, or to proposed charges of recently approved Certificates of Need. If applicable, compare the proposed charges of the project to the current Medicare allowable fee schedule by common procedure terminology (CPT) code(s).

**RESPONSE**: Lebanon PET Scan Center, CN1905-018 was approved September 28, 2019 with a gross charge of \$5,375 per procedure. This Tennessee Oncology-affiliated facility will provide principally cancer PET/CT services whereas the STW PET/CT will provide principally cardiac PET/CT services.

The STW PET/CT will bill two principal CPT codes, 78491 (PET rest/stress) and 78459 (FDG viability study). Gross charges are \$2,553 and \$2,282, respectively, with current Medicare allowable charges of \$1,276 and \$1,141, respectively.

- **6. A**. Discuss how projected utilization rates will be sufficient to support financial performance.
  - 1) Noting when the project's financial breakeven is expected, and

<u>RESPONSE</u>: The STW PET/CT project is expected to breakeven in its first year of operation.

2) Demonstrating the availability of sufficient cash flow until financial viability is achieved.

Provide copies of the balance sheet and income statement from the most recent reporting period of the institution and the most recent audited financial statements with accompanying notes, if applicable. For all projects, provide financial information for the corporation, partnership, or principal parties that will be a source of funding for the project. Copies must be inserted at the end of the application, in the correct alphanumeric order and labeled as Attachment Section B-Economic Feasibility-6A.

<u>Response</u>: The STW project is being undertaken to enhance cardiac nuclear medicine studies and will replace an eleven year old dual SPECT general unit with a cardiac PET/CT. As indicated in the Projected Data Chart, STW's projected utilization will be sufficient to achieve financial breakeven in the first year of operation.

STW, Saint Thomas Health and Ascension are the principal and related parties that will be the source of funding for the project. The substantial resources of these organizations are documented in the attachments and will sustain the start up of the STW PET/CT.

- Ascension: Tab 11 Attachment B-Economic-6A
- Saint Thomas West: Tab 12 Attachment B-Economic-6A
- **B.** Net Operating Margin Ratio: The Net Operating Margin Radio demonstrates how much revenue is left over after all the variable or operating costs have been paid. The formula for this ratio is: (Earnings before interest, Taxes, and Depreciation/Net Operating Revenue).

Utilizing information from the Historical and Projected Data Charts please report the net operating margin ratio trends in the following tables. Complete Project Only Chart and Total Facility Chart, if applicable.

**Project Only Chart** 

Year	2nd Previous Year to Most Recent Year Year	1st Previous Year to Most Recent Year Year	Most Recent Year Year	Projected Year 1 Year <u>2020</u>	Projected Year 2 Year <u>2021</u>
Net Operating Margin Ratio	N/A	N/A	N/A	60.6%	66.7%

**Total Facility Chart** 

Year	2nd Previous Year to Most Recent Year Year 2017	1st Previous Year to Most Recent Year Year 2018	Most Recent Year Year <u>2019</u>	Projected Year 1 Year <u>2020</u>	Projected Year 2 Year <u>2021</u>
Net Operating Margin Ratio	17.7%	18.8%	18.1%	17.4%	17.3%

**C.** Capitalization Ratio: The Long-term debt to capitalization ratio measures the proportion of debt financing in a business's permanent (long-term) financing mix. This ratio best measures a business's true capital structure because it is not affected by short-term financing decisions. The formula for this ratio is: ((Long-Term Debt)/Long-Term Debt + Total Equity {Net Assets}) X 100.

For self or parent company funded projects, provide the capitalization ratio using the most recent year available from the funding entity's audited balance sheet, if applicable. Capitalization Ratios are not expected from outside the company lenders that provide funding. This question is applicable to all applications regardless of whether or not the project is being partially or totally funded by debt financing.

<u>RESPONSE</u>: Ascension, the parent of STW and Saint Thomas Health, is appropriately capitalized to undertake the proposed PET/CT project. Please refer to the exhibit below.

# **Ascension Capitalization Ratio Calculation**

Capitalization Ratio	23.6%	21.8%
Subtotal	30,241	26,114
Total net assets	23,118	20,414
Long-term debt	\$ 7,124	\$ 5,699
Dollars in (\$millions)	2018	2017

Source: Audited Financial Statements, Consolidated Balance Sheet

7. Discuss the project's participation in state and federal revenue programs, including a description of the extent to which Medicare, TennCare/Medicaid and medically indigent patients will be served by the project. Report the estimated gross operating revenue dollar amount and percentage of projected gross operating revenue anticipated by payor classification for the first year of the project by completing the table below. Complete Project Only Chart and Total Facility Chart, if applicable.

**RESPONSE:** STW participates in state and federal revenue programs such as Medicare and, TennCare/Medicaid. Consistent with the mission of Saint Thomas Health and Ascension, STW provides charity and indigent care according to the following policies. Similarly, STW participates in a number of managed care programs.

• Financial Assistance: Tab 13 – Attachment B-Economic-7

Managed Care: Tab 14 – Attachment B-Economic-7

Applicant's Projected Payor Mix, Year 1
Project Only Chart

Payor Source	Projected Gross Operating Revenue	As a % of total
Medicare/Medicare Managed Care	7,245,925	49.0%
TennCare/Medicaid	739,380	5.0%
Commercial/Other Managed Care	5,619,288	38.0%
Self-Pay	1,035,132	7.0%
Other (Specify)Champus,WorkComp	147,876	1.0%
Total*	14,787,601	100.0%
Charity Care	\$295,752	

<sup>\*</sup>Needs to match Gross Operating Revenue Year One on Projected Data Chart

Applicant's Projected Payor Mix, Year 1
Total Facility Chart

Payor Source	Projected Gross Operating Revenue	As a % of total
Medicare/Medicare Managed Care	1,478,730,006	61.8%
TennCare/Medicaid	126,816,651	5.3%
Commercial/Other Managed Care	653,225,391	27.3%
Self-Pay	102,888,981	4.3%
Other: Champus, Work Comp, Othr Op	31,105,971	1.3%
Total*	\$2,392,767,000	100.0%
Charity Care	\$77,118,000	

<sup>\*</sup>Needs to match Gross Operating Revenue Year One on Projected Data Chart

8. Provide the projected staffing for the project in Year 1 and compare to the current staffing for the most recent 12-month period, as appropriate. This can be reported using full-time equivalent (FTEs) positions for these positions. Identify projected salary amounts by position classifications and compare the clinical staff salaries to prevailing wage patterns in the proposed service area as published by the Department of Labor & Workforce Development and/or other documented sources, such as the US Department of Labor. Wage data pertaining to healthcare professions can be found at the following link:

https://www.bls.gov/oes/current/oes tn.htm.

	Position Classification	Existing FTEs (enter year)	Projected FTEs Year 1	Average Wage (Contractual Rate)	Area Wide/Statewide Average Wage
A.	Direct Patient Care Positions				
	RN/Nuclear Tech	0.0	4.0	\$42.59	\$29.96
	Position 2				
	Position "etc."				
	Total Direct Patient Care Positions	0.0	4.0	\$42.59	\$29.96

B.	Non-Patient Care Positions				
	Position 1				- + - 1   1   1   1   1   1   1   1   1   1
	Position 2				
	Position "etc."				
	Total Non-Patient Care Positions				
	Total Employees (A+B)				
C.	Contractual Staff				
	Total Staff (A+B+C)	0.0	4.0	\$42.59	\$29.96

- **9.** What alternatives to this project were considered? Discuss the advantages and disadvantages of each, including but not limited to:
  - **A.** The availability of less costly, more effective and/or more efficient methods of providing the benefits intended by the project. If development of such alternatives is not practicable, justify why not, including reasons as to why they were rejected.

**RESPONSE:** As the flagship of Saint Thomas Health's cardiology service line, the STW project is being undertaken to enhance cardiac nuclear medicine studies and will replace an eleven year old dual SPECT general unit with a cardiac PET/CT. Other alternatives are not clinically appropriate for meeting patient needs.

**B.** Document that consideration has been given to alternatives to new construction, e.g., modernization or sharing arrangements.

**RESPONSE:** Not applicable. The project involves renovations to existing facility space.

#### **QUALITY STANDARDS**

1. Per PC 1043, Acts of 2016, any receiving a CON after July 1, 2016 must report annually using forms prescribed by the Agency concerning continued need and appropriate quality measures Please verify that annual reporting will occur.

**Response:** STW will continue to provide the Tennessee Health Services and Development Agency and/or the reviewing agency information concerning the number of patients treated, the number, and type of procedures performed, and other data as required.

- 2. Quality-The the proposal shall provide health care that meets appropriate quality standards. Please address each of the following questions:
  - **A.** Does the applicant commit to the following?
    - 1) Maintaining the staffing comparable to the staffing chart presented in its CON application;

<u>RESPONSE</u>: The applicant plans to maintain staffing comparable to the staffing chart presented in this CON application.

2) Obtaining and maintaining all applicable state licenses in good standing;

<u>RESPONSE</u>: The applicant plans to maintain all applicable state licenses in good standing.

3) Obtain and maintaining TennCare and Medicare certification(s), if participation in such programs was indicated in the application;

RESPONSE: The applicant plans to maintain TennCare and Medicare certifications.

4) For an existing healthcare institution applying for a CON - Has it maintained substantial compliance with applicable federal and state regulation for the three years prior to the CON application. In the event of non-compliance, the nature of non-compliance and corrective action should be discussed to include any of the following: suspension of admissions, civil monetary penalties, notice of 23-day or 90-day termination proceedings from Medicare/Medicaid/TennCare, revocation/denial of accreditation, or other similar actions and what measures the applicant has or will put into place to avoid similar findings in the future

<u>RESPONSE</u>: The applicant has maintained substantial compliance with applicable federal and state regulation for the three years prior to the CON application.

5) For an existing healthcare institution applying for a CON - Has the entity been decertified within the prior three years? If yes, please explain in detail. (This provision shall not apply if a new, unrelated owner applies for a CON related to a previously decertified facility)

**RESPONSE:** The applicant has not been decertified within the prior three years.

- **B.** Respond to all of the following and for such occurrences, identify, explain and provide documentation:
  - 1) Has any of the following:
    - a. Any person(s) or entity with more than 5% ownership (direct or indirect) in the applicant (to include any entity in the chain of ownership for applicant);
    - b. Any entity in which any person(s) or entity with more than 5% ownership (direct or indirect) in the applicant (to include any entity in the chain of ownership for applicant) has an ownership interest of more than 5%; and/or
    - c. Any physician or other provider of health care, or administrator employed by any entity in which any person(s) or entity with more than 5% ownership in the applicant (to include any entity in the chain of ownership for applicant) has an ownership interest of more than 5%.

**RESPONSE:** Acknowledged. Ownership in the applicant has been identified.

- 2) Been subjected to any of the following:
  - a. Final Order or Judgment in a state licensure action;
  - b. Criminal fines in cases involving a Federal or State health care offense;
  - c. Civil monetary penalties in cases involving a Federal or State health care offense;
  - d. Administrative monetary penalties in cases involving a Federal or State health care offense;
  - e. Agreement to pay civil or administrative monetary penalties to the federal government or any state in cases involving claims related to the provision of health care items and services; and/or
  - f. Suspension or termination of participation in Medicare or Medicaid/TennCare programs.
  - g. Is presently subject of/to an investigation, regulatory action, or party in any civil or criminal action of which you are aware.
  - h. Is presently subject to a corporate integrity agreement.

**RESPONSE:** Neither Saint Thomas West Hospital nor Saint Thomas Health are subject to any of the actions identified above in subparts a-h.

C. Does the applicant plan, within 2 years of implementation of the project, to participate in self-assessment and external assessment against nationally available benchmark data to accurately assess its level of performance in relation to established standards and to implement ways to continuously improve?

Note: Existing licensed, accredited and/or certified providers are encouraged to describe their process for same.

**RESPONSE:** The applicant plans to continue to participate in self-assessment and external assessment described above via Joint Commission, Medicare, licensure and other forms of review.

Please complete the chart below on accreditation, certification, and licensure plans.

1) If the applicant does not plan to participate in these type of assessments, explain why since quality healthcare must be demonstrated.

Credential	Agency	Status (Active or Will Apply)
Licensure	■ Health  □ Intellectual and Developmental Disabilities  □ Mental Health and Substance Abuse Services	Active
Certification	<ul><li>■ Medicare</li><li>■ Medicaid/TennCare</li><li>□ Other</li></ul>	Active
Accreditation	■ Joint Commission	Active

2) Based upon what was checked/completed in above table, will the applicant accept a condition placed on the certificate of need relating to obtaining/maintaining license, certification, and/or accreditation?

**RESPONSE:** The applicant has a history of maintaining appropriate license, certification, and/or accreditation and has no plans to deviate from these policies.

**D.** The following list of quality measures are service specific. Please indicate which standards you will be addressing in the annual Continuing Need and Quality Measure report if the project is approved.

spe sur	For Ambulatory Surgical Treatment Center projects: Estimating the number of physicians by specialty expected to utilize the facility, developing criteria to be used by the facility in extending surgical and anesthesia privileges to medical personnel, and documenting the availability of appropriate and qualified staff that will provide ancillary support services, whether on- or off-site?				
For	Cardiac Catheterization projects:				
a.	Documenting a plan to monitor the quality of its cardiac catheterization program, including but not limited to, program outcomes and efficiencies; and				
b.	Describing how the applicant will agree to cooperate with quality enhancement efforts sponsored or endorsed by the State of Tennessee; and				
c.	Describing how cardiology staff will be maintaining:				
d.	Adult Program: 75 cases annually averaged over the previous 5 years;				
e.	Pediatric Program: 50 cases annually averaged over the previous 5 years.				
For	Open Heart projects:				
f.	Describing how the applicant will staff and maintain the number of who will perform the volume of cases consistent with the State Health Plan (annual average of the previous 2				

years), and maintain this volume in the future;
g. Describing how at least a surgeon will be recruited and retained (at least one shall have 5 years experience);
h. Describing how the applicant will participate in a data reporting, quality improvement, outcome monitoring, and external assessment system that benchmarks outcomes based on national norms (demonstrated active participation in the STS National Database is expected and shall be considered evidence of meeting this standard).
For Comprehensive Inpatient Rehabilitation Services projects: Retaining or recruiting a physiatrist?
For Home Health projects: Documenting the existing or proposed plan for quality data reporting, quality improvement, and an outcome and process monitoring system.
For Hospice projects: Documenting the existing or proposed plan for quality data reporting, quality improvement, and an outcome and process monitoring system.
For Megavoltage Radiation Therapy projects: Describing or demonstrating how the staffing and quality assurance requirements will be met of the American Society of Therapeutic Radiation and Oncology (ASTRO), the American College of Radiology (ACR), the American College of Radiation Oncology (ACRO), National Cancer Institute (NCI), or a similar accrediting authority.
For Neonatal Intensive Care Unit projects: Documenting the existing or proposed plan for data reporting, quality improvement, and outcome and process monitoring systems; document the intention and ability to comply with the staffing guidelines and qualifications set forth by the Tennessee Perinatal Care System Guidelines for Regionalization, Hospital Care Levels, Staffing and Facilities; and participating in the Tennessee Initiative for Perinatal Quality Care (TIPQC).
For Nursing Home projects: Documenting the existing or proposed plan for data reporting, quality improvement, and outcome and process monitoring systems, including in particular details on its Quality Assurance and Performance Improvement program.
For Inpatient Psychiatric projects:
Describing or demonstrating appropriate accommodations for:
<ul> <li>Seclusion/restraint of patients who present management problems and children who need quiet space, proper sleeping and bathing arrangements for all patients);</li> </ul>
Proper sleeping and bathing arrangements;
<ul> <li>Adequate staffing (i.e. that each unit will be staffed with at least two direct patient care staff, one of which shall be a nurse, at all times);</li> </ul>
A staffing plan that will lead to quality care of the patient population served by the project.
<ul> <li>An existing or proposed plan for data reporting, quality improvement, and outcome and process monitoring systems; and</li> </ul>
<ul> <li>If other psychiatric facilities are owned or administered, providing information on satisfactory surveys and quality improvement programs at those facilities.</li> </ul>
Involuntary admissions if identified in CON criteria and standard review

	For Freestanding Emergency Department projects: Demonstrating that it will be accredited w									
	the Joint Commission or other applicable accrediting agency, subject to the same accrediting									
	standards as the licensed hospital with which it is associated.									
	For Organ Transplant projects: Describing how the applicant will achieve and maintain									
	institutional membership in the national Organ Procurement and Transportation Network (OPTN)									
	currently operating as the United Network for Organ Sharing (UNOS), within one year of program									
	initiation. Describing how the applicant shall comply with CMS regulations set forth by 42 CFR									
	Parts 405, 482, and 498, Medicare Program; Hospital Conditions of Participation: Requirements									
	for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants.									
	For Relocation and/or Replacement of Health Care Institution projects: Describing how facility									
ļ.	and/or services specific measures will be met.									

# CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

The responses to this section of the application helps determine whether the project will contribute to the orderly development of healthcare within the service area.

1. List all existing health care providers (i.e., hospitals, nursing homes, home care organizations, etc.), managed care organizations, alliances, and/or networks with which the applicant currently has or plans to have contractual and/or working relationships, that may directly or indirectly apply to the project, such as, transfer agreements, contractual agreements for health services.

**RESPONSE**: Saint Thomas West is one of nine hospitals in Tennessee under the Saint Thomas Health umbrella. These hospitals are:

- Saint Thomas Midtown Hospital in Nashville (formerly Baptist Hospital)
- Saint Thomas West Hospital in Nashville (formerly Saint Thomas Hospital)
- Saint Thomas Hospital for Specialty Surgery in Nashville
- Saint Thomas Rutherford Hospital in Murfreesboro (formerly Middle Tennessee Medical Center)
- Saint Thomas Hickman Hospital in Centerville (formerly Hickman Community Hospital)
- Saint Thomas Highlands Hospital in Sparta (formerly Highlands Medical Center)
- Saint Thomas River Park Hospital in McMinnville (formerly River Park Hospital)
- Saint Thomas Stones River Hospital in Woodbury (formerly Stones River Hospital)
- Saint Thomas DeKalb Hospital in Smithville (formerly DeKalb Community Hospital)

Also included is Saint Thomas Medical Partners, a physician-led medical group providing primary care, specialty services, medical imaging, outpatient services and community-based medical practices through Middle Tennessee and Southern Kentucky.

Managed care relationships are provided in Tab 14 – Attachment B-Economic-7.

2. Describe the effects of competition and/or duplication of the proposal on the health care system, including the impact to consumers and existing providers in the service area. Discuss any instances of competition and/or duplication arising from your proposal including a description of the effect the proposal will have on the utilization rates of existing providers in the service area of the project.

# A. Positive Effects

<u>Response</u>: As the flagship of the Saint Thomas Health cardiology service line, Saint Thomas West Hospital ("STW") is proposing to replace an eleven year old dual SPECT general unit with a cardiac PET/CT scanner. This project is being undertaken to enhance cardiac nuclear medicine studies. Other alternatives are not clinically appropriate for meeting patient needs.

According to TDOH, diseases of the heart are the leading cause of death in Tennessee. Data indicate that cardiac mortality increased 8.1% from 2012 to 2017. Twenty-five service area counties (68% of the total) have cardiac death rates greater than the Tennessee rate, with six exceeding the Tennessee rate by more than 150% and another two by more than 200%. Please refer to the documentation in **TAB 21**.

Approval of this project will provide an important tool in combating heart disease and cardiac deaths in Tennessee.

These and other positive effects of the STW project are described in the letters of support submitted with this application. Please refer to **Tab 22**.

# B. Negative Effects

**RESPONSE**: PET/CT procedures in Tennessee have been growing at nearly 10% per year. As cardiac and cancer incidence rates increase, this growth is projected to increase into the future. In sharp contrast, service area resident PET/CT procedures have increased at a mere 3.86% per year, from 9,626 in 2015, to 10,057 in 2016, to 10,384 in 2017.

The 10.4 existing PET/CT scanner in the service area averaged 1,164 procedures per scanner in 2017. While this is less than the 1,600 procedure minimum, PET/CT utilization has been increasing at nearly 10% per year. At the historical 9.63% annual growth rate, which includes non-resident utilization, the existing PET/CT scanners in the service area are projected to average 2,021 procedures per scanner by the 2023 planning horizon. Even including the recently approved PET/CT scanner for Lebanon PET Scan Center and this proposed STW PET/CT scanner, 2023 PET/CT utilization is projected to average 1,695 procedures per scanner. This exceeds the 80% minimum requirement and will mitigate any potential negative effects on existing PET/CT providers.

**3. A.** Discuss the availability of and accessibility to human resources required by the proposal, including clinical leadership and adequate professional staff, as per the State of Tennessee licensing requirements, CMS, and/or accrediting agencies requirements, such as the Joint Commission and Commission on Accreditation of Rehabilitation Facilities.

**RESPONSE:** STW has existing nuclear imaging capabilities and will draw upon the physician leadership of Dante J. Graves, MD for this project. Similarly, STW will leverage existing nuclear imaging staffing and on-going recruitment/retention efforts to obtain the 4.0 additional FTEs required for this project.

**B.** Document the category of license/certification that is applicable to the project and why. These include, without limitation, regulations concerning clinical leadership, physician supervision, quality assurance policies and programs, utilization review policies and programs, record keeping, clinical staffing requirements, and staff education.

**RESPONSE:** STW already maintains active nuclear medicine and diagnostic imaging services. It understands the licensure and certification requirements for PET/CT compliance.

**C.** Discuss the applicant's participation in the training of students in the areas of medicine, nursing, social work, etc. (e.g., internships, residencies, etc.).

<u>RESPONSE</u>: STW actively participates in the training of students in these areas. Please see TAB 18 – Attachment B-Contribution-3C.

## 4. Outstanding Projects:

**A.** Complete the following chart by entering information for each applicable outstanding CON by applicant or share common ownership; and

Outstanding Projects									
CON Number	Project Name	Date Approved	*Annual Progress Report(s)		Expiration Date				
			Due Date	Date Filed	<u> </u>				
CN1905-019A	Saint Thomas Rehabilitation Hospital, LLC	08/28/19							
CN1806-023A	Northridge Surgery Center	10/24/18							
CN1806-022A	Cumberland Behavioral Health	10/24/18							
CN1805-021A	Premier Radiology	8/22/18			12/1/18				
CN1803-014A	Premier Radiology	6/27/18			8/1/20				
CN1707-022A	Saint Thomas Surgery Center New Salem	10/25/17			12/1/20				
CN1707-021A	Saint Thomas Rutherford Hospital	10/25/17			12/1/20				
CN1608-031A	Providence Surgery Ctr	12/14/16	Operational		2/1/19				

<sup>\*</sup> Annual Progress Reports – HSDA Rules require that an Annual Progress Report (APR) be submitted each year. The APR is due annually until the Final Project Report (FPR) is submitted (FPR is due within 90 ninety days of the completion and/or implementation of the project). Brief progress status updates are requested as needed. The project remains outstanding until the FPR is received.

# **B.** Describe the current progress, and status of each applicable outstanding CON.

CN1905-019A was recently approved. The Saint Thomas Rehabilitation Hospital, LLC application is to establish a new, freestanding 40-bed Inpatient Rehabilitation Facility that is a joint venture owned by affiliates of Saint Thomas Health and Kindred Healthcare. The location will be on the campus of Saint Thomas Midtown Hospital. Saint Thomas Midtown Hospital will cease operation of its existing 24-bed acute rehabilitation unit, de-license these beds, and de-license an additional 16 medical surgical beds.

CN1806-023A was recently approved. The Northridge Surgery Center application is to relocate its existing multi-specialty ambulatory surgical treatment center with 5 operating rooms and 1 procedure room from 647 Myatt Drive in Madison (Davidson County), Tennessee,37115 to leased space in a new facility to be constructed at 601 Saundersville Road, Hendersonville (Sumner County), TN, 37075. When complete, NSC's new replacement ASTC will include three operating rooms and one procedure room.

CN1806-022A was recently approved. The Cumberland Behavioral Health application is for the establishment of a 76-bed mental health hospital located at 300 Great Circle Road,

Nashville (Davidson County), TN. The hospital will contain 40 adult inpatient psychiatric beds and 36 geriatric inpatient psychiatric beds. Upon approval, Saint Thomas West Hospital will close its 24-bed psychiatric unit, surrendering the beds.

CN11805-021A was recently approved. The Premier Radiology application was for the establishment of an Outpatient Diagnostic Center, initiation of MRI services, and acquisition of a fixed 1.5T MRI unit in a building under construction at 3754 Murfreesboro Pike, Antioch (Davidson county), TN.

CN1803-014A was recently approved. The Premier Radiology application for the establishment of an outpatient diagnostic center (ODC), the initiation of MRI services, and the acquisition of a fixed 1.5 Tesla MRI unit and fixed 16 slice CT unit at a new building under construction at 110 St. Blaise Road, Gallatin (Sumner County), TN, 37066. In addition to MRI and CT, the ODC will provide x-ray, mammography, and ultrasound services, which will support primary care services at the Saint Thomas Medical partners-Gallatin Care Center.

CN1707-022A was updated on march 25,2018 from the supplemental response for CN1803-004, land was acquired for the site in March 2018, architectural plans are under development and review. The Saint Thomas Surgery Center New Salem was an application for the establishment of a multi-specialty ambulatory surgery treatment center (ASTC) with two operating rooms and one procedure room located at 2779 New Salem Road, Murfreesboro (Rutherford County),TN 37218.

CN1707-021A was updated on May 25,2018 stating that the project is on time and within budget and expected to begin in October 2018. The Saint Thomas Rutherford Hospital application was for the addition of 72 beds which will increase the licensed bed capacity from 286 beds to 358 beds.

CN1608-031A has been open and operating since October 4, 2018 that the project is complete and multi-specialty ASTC services are being provided. A Final Project Report is pending. The Providence Surgery Center application was for the conversion of an existing ambulatory surgical treatment center, which is limited to orthopedic and pain procedures, to a multi-specialty ASTC located at 5002 Crossing Circle, Suite 110, Mount Juliet, (Wilson County),TN 37122. The ASTC will include two operating rooms and one ASTC.

- 5. Equipment Registry For the applicant and all entities in common ownership with the applicant.
  - **A.** Do you own, lease, operate, and/or contract with a mobile vendor for a Computed Tomography scanner (CT), Linear Accelerator, Magnetic Resonance Imaging (MRI), and/or Positron Emission Tomographer (PET)? Yes, Saint Thomas Health is a joint venture owner in Middle Tennessee Imaging.
  - **B.** If yes, have you submitted their registration to HSDA? If you have, what was the date of submission? Yes, various dates.
  - **C.** If yes, have you submitted your utilization to Health Services and Development Agency? If you have, what was the date of submission? <u>Yes, various dates.</u>

### **SECTION C: STATE HEALTH PLAN QUESTIONS**

T.C.A. §68-11-1625 requires the Tennessee Department of Health's Division of Health Planning to develop and annually update the State Health Plan (found at <a href="https://www.tn.gov/health/health-program-areas/health-planning/state-health-plan.html">https://www.tn.gov/health/health-program-areas/health-planning/state-health-plan.html</a>) The State Health Plan guides the State in the development of health care programs and policies and in the allocation of health care resources in the State, including the Certificate of Need program. The <a href="https://www.tn.gov/health/health-program-areas/health-plan.html">https://www.tn.gov/health/health-program-areas/health-plan.html</a>) The State Health Plan guides the State in the State, including the Certificate of Need program. The <a href="https://www.tn.gov/health/health-program-areas/health-plan.html">https://www.tn.gov/health/health-program-areas/health-plan.html</a>) The State Health Plan guides the State in the State, including the Certificate of Need program. The <a href="https://www.tn.gov/health/health-program-areas/health-plan.html">https://www.tn.gov/health/health-program-areas/health-plan.html</a>) The State Health Plan guides the State in the State, including the Certificate of Need program. The <a href="https://www.tn.gov/health/health-program-areas/health-plan.html">https://www.tn.gov/health/health-program-areas/health-plan.html</a>) The State Health Plan guides the State in the State in the State Health Plan guides the State in the State in the State Health Plan guides the State in the

Discuss how the proposed project will relate to the <u>5 Principles for Achieving Better Health</u> found in the State Health Plan.

1. The purpose of the State Health Plan is to improve the health of Tennesseans.

RESPONSE: According to TDOH, diseases of the heart are the leading cause of death in Tennessee. Data indicate that cardiac mortality increased 8.1% from 2012 to 2017. Twenty-five service area counties (68% of the total) have cardiac death rates greater than the Tennessee rate, with six exceeding the Tennessee rate by more than 150% and another two by more than 200%. Please refer to the documentation in TAB 21.

As the flagship of the Saint Thomas Health cardiology service line, Saint Thomas West Hospital ("STW") is proposing to replace an eleven year old dual SPECT general unit with a cardiac PET/CT scanner. This project is being undertaken to enhance cardiac nuclear medicine studies. Other alternatives are not clinically appropriate for meeting patient needs.

Approval of this project will provide an important tool in combating heart disease and cardiac deaths in Tennessee.

2. Every citizen should have reasonable access to health care.

**RESPONSE:** The actual service area PET/CT resident utilization rate has been lower than the statewide average, reflecting a lack of access to PET/CT services in the service area. PET/CT procedures in Tennessee have been growing at nearly 10% per year. As cardiac and cancer incidence rates increase, this growth is projected to increase into the future. In sharp contrast, service area resident PET/CT procedures have increased at a mere 3.86% per year, from 9,626 in 2015, to 10,057 in 2016, to 10,384 in 2017. It is reasonable to project that the service area resident utilization rate should mirror that of the Tennessee resident use rate. Approval of the STW cardiac PET/CT project will help provide reasonable access to health care to combat heart disease and cardiac deaths in Tennessee.

3. The state's health care resources should be developed to address the needs of Tennesseans while encouraging competitive markets, economic efficiencies and the continued development of the state's health care system.

**RESPONSE**: The STW cardiac PET/CT will help address the growing need for advanced imaging services in the service area. As illustrated in Section B, the 10.4 existing PET/CT scanners in the service area averaged 1,164 procedures per scanner in 2017. While this is less than the 1,600 procedure minimum, PET/CT utilization has been increasing at nearly 10% per year. At the historical 9.63% annual growth rate, which includes non-resident utilization, the existing PET/CT scanners in the service area are projected to average 2,021 procedures per scanner by the 2023

planning horizon. Even including the recently approved PET/CT scanner for Lebanon PET Scan Center and this proposed STW PET/CT scanner, 2023 PET/CT utilization is projected to average 1,695 procedures per scanner. This exceeds the 80% minimum requirement.

4. Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers.

<u>RESPONSE</u>: STW has existing nuclear imaging capabilities and will draw upon the physician leadership of Dante J. Graves, MD and his team to provide quality cardiac PET/CT services.

5. The state should support the development, recruitment, and retention of a sufficient and quality health care workforce.

<u>RESPONSE</u>: STW supports this statewide goal by actively participating in the training of healthcare professionals. Please see TAB 18 – Attachment B-Contribution-3C.

#### PROOF OF PUBLICATION

Attach the full page of the newspaper in which the notice of intent appeared with the mast and dateline intact or submit a publication affidavit from the newspaper that includes a copy of the publication as proof of the publication of the letter of intent.

Date LOI was Submitted:	September 10, 2019	
Date LOI was Published:	September 10, 2019	

50

#### **NOTIFICATION REQUIREMENTS**

- 1. T.C.A. §68-11-1607(c)(9)(A) states that "...Within ten (10) days of the filing of an application for a nonresidential substitution-based treatment center for opiate addiction with the agency, the applicant shall send a notice to the county mayor of the county in which the facility is proposed to be located, the state representative and senator representing the house district and senate district in which the facility is proposed to be located, and to the mayor of the municipality, if the facility is proposed to be located within the corporate boundaries of a municipality, by certified mail, return receipt requested, informing such officials that an application for a nonresidential substitution-based treatment center for opiate addiction has been filed with the agency by the applicant."
- 2. T.C.A §68-11-1607(c)(9)(B) states that "... If an application involves a healthcare facility in which a county or municipality is the lessor of the facility or real property on which it sits, then within ten (10) days of filing the application, the applicant shall notify the chief executive officer of the county or municipality of the filing, by certified mail, return receipt requested."

Failure to provide the notifications described above within the required statutory timeframe will result in the voiding of the CON application.

Please provide documentation of these notifications.

#### **DEVELOPMENT SCHEDULE**

T.C.A. §68-11-1609(c) provides that a Certificate of Need is valid for a period not to exceed three (3) years (for hospital projects) or two (2) years (for all other projects) from the date of its issuance and after such time shall expire; provided, that the Agency may, in granting the Certificate of Need, allow longer periods of validity for Certificates of Need for good cause shown. Subsequent to granting the Certificate of Need, the Agency may extend a Certificate of Need for a period upon application and good cause shown, accompanied by a non-refundable reasonable filing fee, as prescribed by rule. A Certificate of Need which has been extended shall expire at the end of the extended time period. The decision whether to grant such an extension is within the sole discretion of the Agency, and is not subject to review, reconsideration, or appeal.

- 1. Complete the Project Completion Forecast Chart on the next page. If the project will be completed in multiple phases, please identify the anticipated completion date for each phase.
- 2. If the CON is granted and the project cannot be completed within the standard completion time period (3 years for hospital projects and 2 years for all others), please document why an extended period should be approved and document the "good cause" for such an extension.

# PROJECT COMPLETION FORECAST CHART

Assuming the Certificate of Need (CON) approval becomes the final HSDA action on the date listed in Item 1. below, indicate the number of days from the HSDA decision date to each phase of the completion forecast.

Phase	<u>Days</u> <u>Required</u>	Anticipated Date [Month/Year]
Initial HSDA decision date		Dec-19
Architectural and engineering contract signed		Jan-20
Construction documents approved by the Tennessee     Department of Health	30	May-20
4. Construction contract signed	60	Mar-20
5. Building permit secured	30	May-20
6. Site preparation completed	30	May-20
7. Building construction commenced	30	May-20
8. Construction 40% complete	24	Jun-20
9. Construction 80% complete	24	Jul-20
10. Construction 100% complete (approved for occupancy)	12	Sep-20
11. *Issuance of License	14	Oct-20
12. *Issuance of Service	14	Oct-20
13. Final Architectural Certification of Payment	60	Nov-20
14. Final Project Report Form submitted (Form HR0055)	30	Dec-20

<sup>\*</sup>For projects that <u>DO NOT</u> involve construction or renovation, complete Items 11 & 12 only.

NOTE: If litigation occurs, the completion forecast will be adjusted at the time of the final determination to reflect the actual issue date

**AFFIDAVIT** 

STATE OF Tennessee
COUNTY OF _Davidson
Lacey Benford, being first duly sworn, says that he/she is the
applicant named in this application or his/her/its lawful agent, that this project will be completed in
accordance with the application, that the applicant has read the directions to this application, the
Rules of the Health Services and Development Agency, and T.C.A. §68-11-1601, et seq., and that
the responses to this application or any other questions deemed appropriate by the Health
Services and Development Agency are true and complete.    Ohear, Stateon Signature/Title   Assentin Country   Signature   Assentin Country   Assentin Country   Signature   Assentin Country   Assentin Country   Assentin Country   Assentin Country
Sworn to and subscribed before me this 12 day of Sept., 2019 a Notary (Month), (Year)
Public in and for the County/State of Dandfund TN
My commission expires 01 05 , 202   (Year)  Motary Public   Tennessee   Notary Public   Notary

# **TABLE OF CONTENTS**

## **Attachment A**

- Tab 1 Corporate Charter & Certificate of Existence
- Tab 2 Organizational Chart
- Tab 3 Deed
- Tab 4 Plot Plan
- Tab 5 Floor Plan
- Tab 6 Public Transit
- Tab 7 Equipment Quote

## **Attachment B**

- Tab 8 Demographic Table
- Tab 9 Construction Letter
- Tab 10 Funding Letter
- Tab 11 Ascension Financial Statements
- Tab 12 Saint Thomas West Financial Statements
- Tab 13 Patient & Financial Assistance Policies
- Tab 14 Managed Care Contracts
- Tab 15 Quality & Utilization Management Plans
- Tab 16 Hospital Accreditation
- Tab 17 Hospital License
- Tab 18 Training Program Affiliations
- Tab 19 Physician CVs
- Tab 20 Medically Underserved Areas
- Tab 21 Heart Disease Table

# Attachment C

Tab 22 - Support Letters

# **Attachment D**

Tab 23 - Copy of Published Public Notice

Tab 24 - Letter of Intent

# **Attachment A**

Corporate Charter & Certificate of Existence
Organizational Chart
Deed
Floor Plan
Plot Plan
Public Transit
Equipment Quote

**Attachment A-6B-1** 

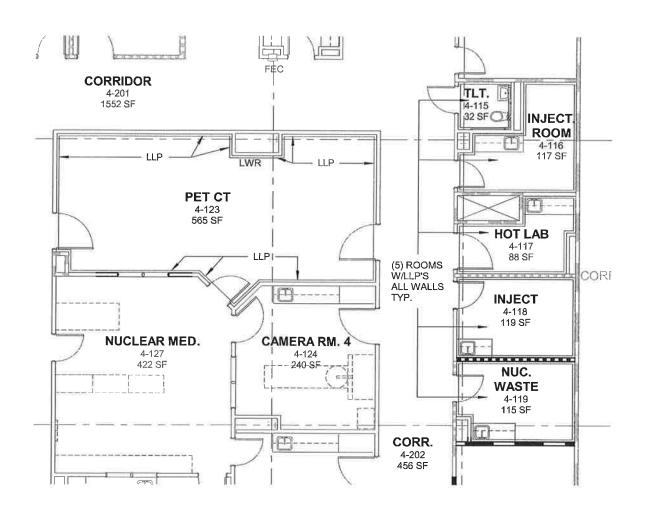
**Plot Plan** 



Tab 5

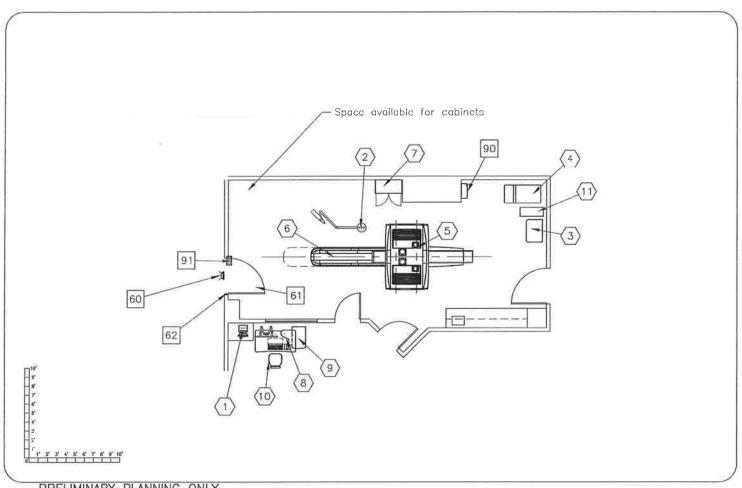
**Attachment A-6B-2** 

Floor Plan



SAINT THOMAS WEST - PET CT EQUIPMENT REPLACEMENT

1/8" = 1'-0"



PRELIMINARY PLANNING ONLY

PROJECT TITLE:

SAINT THOMAS WEST NUCLEAR AREA

NASHVILLE, TN

SCHEME NO.: 19TMA012 DRAWN BY: MLC

THIS LAYOUT **MUST** BE APPROVED BEFORE FINAL DRAWINGS CAN BE STARTED. THANK YOU

CUSTOMER\_ DAIL:

GE INSTALL. SPECIALIST\_ DATE:



# **GE Healthcare**

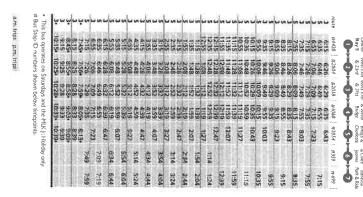
Modality Installation Planning

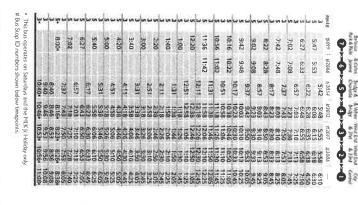
Tab 6

Attachment A-6B-3

**Public Transit** 







#### **EasyRide Commuter Benefits**

Benefits to employers

- Saves tax dollars
- · On-site parking becomes a non-issue
- · Less-stressed employees

Benefits to employees

- · Cuts taxable income
- · Reduces car expenses
- · Arrive at work relaxed

For more information, contact MTA at 615-862-5969 or ask your Human Resources Director about commuter



#### Destination Signs

Every MTA bus is marked with a route number as well as the destination name or area. All express routes are designated by an "X" following the route number if you have questions about where a bus is going, please ask the driver as you board.

#### Snow Route Detours

Be prepared for winter weather and pick up your MTA, snow route detours brochure today Snow route information may be found at MTA displays around town. on MTA buses, online at nashvillenta.org, or by calling Customer Care at 615-862-5950.

The Nashville MTA and Regional Transportation Authority of Middle Tennessee (RTA) make reasonable accommodations in order for individuals with disabilities accommodations in order for moviguals with displaced to fully use framit terricers. All requests should be made in advance by filling out and submitting a Reasonable Accommodation Request form, for more information on Reasonable Accommodations, viot nashvillemsa.org.

TitleVI of the CNR Rights Act of 1964 states that "No Person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of or be subjected to discrimination under any program or activity necessing Federal financial assistance." For more information on Title VI, visit. nashvillemm.org.

#### Fares

Adult - Local, Express, Airport & BRT lite Services \_\_ \$1.70 2nd Ride Transfer (within 2 hours of boarding)...No Charge (uges 65 and older, please show driver proof

of age before depositing fare)
People with Disabilities and Medicare Cardholders \$ .85

(please show driver special identification card before depositing fare) Youth Fare. (ages 19 and younger please alea driver before

depositing fare and be prepared to show proof of age upon request) ... No Charge Children ages 4 and younger....

## Seniors, or People with Disabilities

Medicare cardholders, who are not elderly or disabled, qualify for a reduced MTA fare of 85 cents on MTA buses with their Medicare ID.

Seniors age 65 and older and people with disabilities qualify for a reduced MTA fare of 85 cents on MTA buses with one of the following ID cards: Medicare, Seniors-MTA Golden Age, or driver's license; Disabled-Medicare, MTA Special Service, or other transit ID card for the disabled.

Passengers whose disabilities prevent them from using the large MTA buses may qualify for special door-to-door van service through the MTA AccessRide Program. Please call the MTA AccessRide Office at 615-880-3970 for more information or visit the MTA website at nashvillemta.org

#### MTA Passes

For your convenience, passes are available for purchase at Music City Central (400 Charlotte Avenue), online at nashvillemta.org. or by phone at 615-862-5950. In addition passes may be requested via mail by sending the request to the MTA Administrative Office address.

WEEKENDS & HO

All-Day Pass \$3 25	7-Day Pass \$16,00
All-Day	31-Day Pass\$55.00
Discounted Pass \$2.00	31-Day
All-Day Youth Pass \$2.25	Discounted Pass\$29.00
20-Ride	Quest 7-Day
Local & Express \$32.00	Youth Pass \$10.00
20-Ride	Quest 31-Day
Discounted Pass \$17.00	Youth Pass \$38.00

Cash checks, money orders, and credit cards are accepted for these purchases. A shaping fee will be applied to all mail phone and online orders.

For more information, please call MTA Customer Core at 615-862-5950 or visit our website at nashvillemta org

#### Music City Central

The main transfer station is located at Music City Central (400 Charlotte Avenue).

& All MTA buses are accessible and equipped with bike racks.

#### Hollday Service

On the following major holidays, MTA operates service on a Sunday/Holiday schedule: New Year's Day • Memorial Day • Independence Day •
Labor Day • Thanksgiving • Christmas
 On Martin Luther King Jr. Day MTA operates service on a

#### MTA Office Hours

Customer Care Call Center: 615-862-5950 6:30 am to 8:00 pm. - Monday Friday 8:00 am to 5:00 pm. - Saturday 10:30 am to 2:30 pm. - Sunday

Ticket Sules and Information at Music City Central 400 Charlotte Avenue 600 a.m. to 6:30 p.m. – Monday-Friday 8:00 am to 5:00 pm - Saturday 10:30 am to 2:30 pm - Sunday Closed holidays

Music City Central - Hours of Operation 400 Charlotte Avenue 5.15 a.m. to 11.15 p.m. - Monday Friday 600 a.m. to 10:15 p.m. – Saturday 600 a.m. to 9:15 p.m. – Sundays and holidays Administrative Offices: 615-862-5969 430 Myatt Drive, Nashville, TN 37115 8:00 a.m. to 4:30 p.m. – Monday-Friday Closed weekends and holidays

430 Myaci Drive, Nashville, FN 37115

designed by CHK America - chkamerica.c



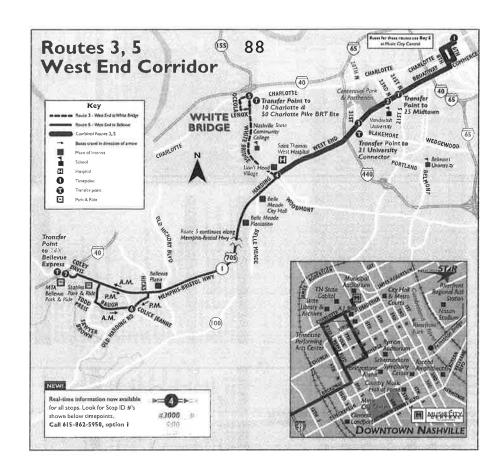
MUSIC CITY CENTRAL - BAY 5 10-15 MIN. WEEKDAYS - 20 MIN. WEEKENDS



Customer Care and & ADA Coordinator 615-862-5950 AccessRicle 615-880-3970

nashvillemta.org MashvilleMTA

Effective October 1, 2017



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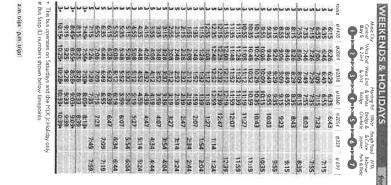
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On school days only, this bus begins service at Martin Luther King Jr.
 Magnet School at 3:10 p.m. and travels directly to Music City Central



Board's which mounts more convenience for you. you can spend less time waiting and near love Aziville MIA, you will know when to go. So and your time, with real-bine branch date from guiez' dixing you better access to your hips уюм хол сви вид опт муеля хол: pns is sq 9|t

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#### **EasyRide Commuter Benefits**

#### Benefits to employers

- Saves tax dollars
- · On-site parking becomes a non-issue
- · Less-stressed employees

#### Benefits to employees

- Cuts taxable income
- · Reduces car expenses
- · Arrive at work relaxed

For more information, contact MTA at 615-862-5969 or ask your Human Resources Director about commuter



#### Destination Signs

Every MTA bus is marked with a route number as well as the destination name or area. All express routes are designated by an "X" following the route number: If you have questions about where a bus is going, please ask the driver as you board.

#### Snow Route Detours

Be prepared for winter weather and pick up your MTA show notes detours brochiere today Show route information may be found at MTA displays around town, on MTA buses, online at restivilients.org, or by calling Customer Care at 615-862-5950.

The Nashville MTA and Regional Transportation Authority of Middle Tennessee (RTA) make reasonable accommodations in order for individuals with disabilities to fully use transit services. All requests should be made in advance by fifting out and submitting a Reasonable Accommodation Request forms for more information on Reasonable Accommodations, visit nashvillemta.org.

Title VI of the CNI Rights Act of 1964 states that "No Person in the United States shall on the ground of race." color or national bright be excluded from participation in, be denied the benefits of, or be subjected to distrimination under any program or activity receiving Federal financial assistance. For more information on Title VI, visit

Adult - Local, Express, Airport & BRT lite Services \_\_ \$1.70 2nd Ride Transfer (within 2 hours of boarding)...No Charge Senior.... (ages 65 and older, please show driver proof

(please show driver special identification card before depositing fare)

Youth Face (ages 19 and younger, please alert driver before

depositing fare and be prepared to show proof of age upon request)

Children ages 4 and younger

#### Seniors, or People with Disabilities

Medicare cardholders, who are not elderly or disabled, qualify for a reduced MTA fare of 85 cents on MTA buses with their Medicare ID.

Seniors age 65 and older and people with disabilities qualify for a reduced MTA fare of 85 cents on MTA buses with one of the following ID cards: Medicare, Seniors-MTA Golden Age, or driver's license; Disabled-Medicare, MTA Special Service, or other transit, ID card for the disabled.

Passengers whose disabilities prevent them from using the large MTA buses may qualify for special door-to-door van service through the MTA AccessRide Program. Please call the MTA AccessRide Office at 615-880-3970 for more information or visit the MTA website at nashvillemta.org

#### MTA Passes

For your convenience, passes are available for purchase at Music City Central (400 Chariotte Avenue), online at nashwillemta.org, or by phone at 615-862-5950.

In addition, passes may be requested via mail by sending the request to the MTA Administrative Office address.

All-Day Pass \$3,25 All-Day	7-Day Pass	\$16.00
	31-Day Pass	\$55.00
	31-Day	
All-Day Youth Pass \$2.25	Discounted Pass	\$29.00
20-Ride	Quest 7-Day	0.117
Local & Express \$32.00	Youth Pass	\$10.00
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#### Music City Central

The main transfer station is located at Music City Central (400 Charlotte Avenue).

& All MTA buses are accessible and equipped with bike racks.

#### Holiday Service

On the following major holidays MTA operates service on

On the following major follows: ITTA operates service on a Sunday/follows schedule:

New Year's Day \* Memorial Day \* Independence Day \* Labor Day \* Transgaving \* Christmas\*

On Martin Luther King & Day MTA operates service on a Structure schedule. Saturday schedule.

#### MTA Office Hours

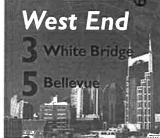
Customer Care Call Center: 615-862-5950 630 a.m. to 8:00 p.m. – Monday Friday 8:00 a.m. to 8:00 p.m. – Saturday 10:30 a.m. to 2:30 p.m. – Sunday Closed holidays

Ticket Sales and Information at Music City Central 400 Charlotte Avenue 400 am to 630 pm – Monday-Enday 800 am to 500 pm – Saturday 1030 am to 230 pm – Sanday Closed holidays

Music City Central – Hours of Operation 400 Charlotte Avenue 515 a.m. to 11:15 pm. – Honday Friday 600 a.m. to 10:15 pm. – Substay 500 a.m. to 9:15 pm. – Substay 500 a.m. to 9:15 pm. – Substay Administrative Offices: 615-862-5969 430 Myatt Drive, Nashville, TN 37115 8:00 a.m. to 4:30 p.m. – Monday-Friday Closed weekends and holidays

### Metropolitan Transit Authority 430 Myatt Drive, Nashville, TN 37115

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MUSIC CITY CENTRAL-BAY 5 10-15 MIN WEEKDAYS - 20 MIN WEEKENDS

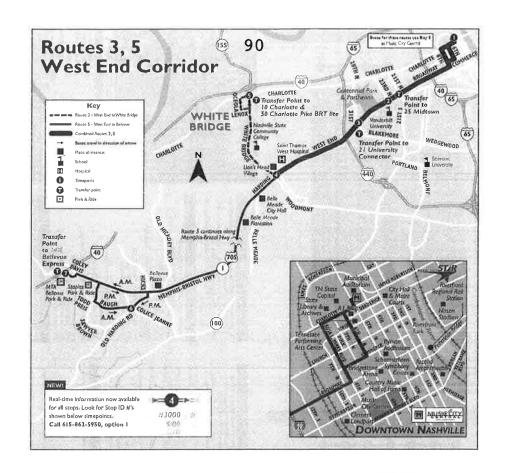


Customer Care and & ADA Coordinator 615-862-5950 615-880-3970 nashvillemta.org

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₩ @NashvilleMTA

Effective October 1, 2017



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8:30	8:44	9:48	8:55		350	9:17	
8:45	8:59 9:13	9:03 9:17	9:10	9:20	10000	0.50	
9:00	9:13	9:17	9:39	9:49		9:46	
9:30	9:43	9:37	9:54	10000		10:16	
9:45	9.58	10:02	10:09	10:19			
10:00	10:13	10:17	10:24	10:49		10:46	
10:15	10:28	10:32	10:39	100		11:16	
10:45	10:58	11:02	11:09	11:19		44.40	
11:00	11:13	11:17	11:24	11:49	-	11:45	
11:30	11:43	11:47	11:54	1111111		12:16	
12:00	11:58	12:02	12:09	12:19	12:40	12:49	
12:15	12:28	12:32	12:39	12:49	12740	12:43	
2:30 2:45	12:43	12:47	12:54		1:10	1219	
12:45	12:58	1:02	1:09	1:19	1140	1:49	
1:15	1:28	1:32	1139	1/49	1040	1,43	
1:15	1:43	3:47	1154		211	2:20	
1:45	1:58	2 02	2:09	2:19	2:43	2:52	
2:00	2:14	2 33	2:25	2:50	2,43	A.JA	
2:30	2:44	7:48	2:57		3:16	3:25	
3.00	3:59	3:03	3112	3:22	3:51	4:00	
3:15	3:30	3:35	3:47	3:57	3131	19,1713	
3:25	3:50	\$145	1:57		4:16	4:25	
3:35	3:50	3:55 4:07	4:07	4:17	4138	4:47	
3:55	4111	4:18	4:30 4:40	4:40	4130	4.40	
4:05	4:21	4:28			4:59	5:08	
4:20	4:36 4:52 5:02	4:43	4:55	5:05	5:29	5:38	
4:35	5:62	4,58 5:08	5:10 5:20	5:30	314.7	3,30	
4:55	5111	5:16	5:28	1	5:47	5:56	
5:05	5:21	5:26 5:35	5:38	5:48	6.06	6:15	
5:25	5:40	5:45	5:56	6:05	0.00	0.13	
5:25 5:35 5:45	5:50 5:59	5:55	6:04	2000	6:22	6:31	
5:45	5:59	6:03	6:11	6:20	6:37	6:46	
6:15	6:27	6:31	6:37	6:45			
6:15	6:27 6:47	6:31	6:37 6:57		7:13	7:21	
6:55	7:07	7:11	7:17	7:25	7:53	8:01	
7:35	7:27	7/31	7:37 7:57	8:05	-623	0,41	
7:55	8:07	8511	8:17		8:33	8:41	
8:15	8:26	9:00	9:06	8:43	9:22	9:30	
9:15	9:26	9:30	9:36	9:43	7.24	7,50	
9:45	9:56	9:59	10:04		10:18	10:26	
10:15	10:26	10:29	10.34	10:41			
	- T100 pt	1 1000	THE PERSON NAMED IN	4 4 1 1 1 1 1 1			

On school days only, this bus begins service at Martin Luther King Jr. Magnet School at 3:10 p.m. and travels directly to Music City Central

Tab 7

# **Attachment B**

Demographic Table
Construction Letter
Funding Letter
Ascension Financial Statements
Saint Thomas West Financial Statements
Patient & Financial Assistance Policies
Managed Care Contracts
Quality & Utilization Management Plans
Hospital Accreditation
Hospital License
Training Program Affiliations
Physician CVs
Medically Underserved Areas
Heart Disease Table

Tab 9

Attachment B-Economic-1E

**Construction Letter** 



September 6, 2019

Ms. Lacey Benford, Strategy Director 102 Woodmont Blvd. Nashville, TN 37205

RE: Certificate of Need: Verification of costs for St Thomas West Hospital

**PetCT Equipment Renovation** 

Dear Ms. Benford:

As I understand the initial scope and schedule, St Thomas West Hospital in Nashville, TN is planning on renovating existing nuclear medicine rooms for a new PetCT scanning room. The renovation assumes a total of approximately 770 square feet within the Level Four Non-Invasive Cardiac Department. Although this initial scope is preliminary I have reviewed the space layout per preliminary GE Equipment Vendor Drawings and believe this scope will address the functional and equipment requirements.

Preliminary construction costs prepared by a General Contractor has estimated the renovation to cost around \$450,000. In my opinion, and based on preliminary assumptions for construction and possible equipment shielding requirements, this current construction estimate along with the total estimated project estimate of \$1,640,673 including fees, equipment, construction and other professional services for the above project description are reasonable, based on similar projects.

The project will be design in accordance with applicable local, state and federal standards and codes, including the adopted edition of the FGI Guidelines for Design and Construction of Health Care Facilities.

Please do not hesitate to contact me if you have any guestions.

Sincerely,

Tab 10

# **Attachment B-Economic-2**

**Funding Letter** 



September 10, 2019

Logan □rant, Executive Director
Health Services and Development Agency
Andrew Jackson State Office □uilding
502 Deaderick Street, 9th Floor
Nashville, TN 37243

RE: Saint Thomas West PET/CT CON Capital Commitment

Dear Mr. □rant:

The purpose of this letter is to confirm to the Health Services and Development Agency that Saint Thomas West Hospital and Saint Thomas Health have sufficient resources available to fund all costs required for the development and establishment of the project referenced above as set forth in the certificate of need application. Cash on hand will be used to fund the project costs of approximately  $\Box 1,700,000$ .

Please let me know if you need any additional information regarding this matter.

Sincerely,

Fahad Tahir, FACHE
President and CEO
Saint Thomas Midtown Hospital
Saint Thomas West Hospital

102 Woodmont Blvd • Suite 800 • Woodmont Centre • Nashville, TN 37205 • STHealth.com

HICKMAN HOSPITAL

MIDTOWN HOSPITAL

**Attachment B-Economic-6A** 

**Ascension Financial Statements** 

CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY INFORMATION

Ascension Health Alliance d/b/a Ascension Years Ended June 30, 2018 and 2017 With Reports of Independent Auditors

# Consolidated Financial Statements and Supplementary Information

Years Ended June 30, 2018 and 2017

# **Contents**

Report of Independent Auditors	3
Consolidated Financial Statements	
Consolidated Balance Sheets	5
Consolidated Statements of Operations and Changes in Net Assets	7
Consolidated Statements of Cash Flows	9
Notes to Consolidated Financial Statements	I 1
Supplementary Information	
Report of Independent Auditors on Supplementary Information	65
Schedule of Net Cost of Providing Care of Persons	
Living in Poverty and Other Community Benefit Programs	66



Ernst & Young LLP The Plaza in Clayton Suite 1300 190 Carondelet Plaza St. Louis, MO 63105-3434 Tel: +1 314 290 1000 Fax: +1 314 290 1882 ev.com

## Report of Independent Auditors

The Board of Directors
Ascension Health Alliance d/b/a Ascension

We have audited the accompanying consolidated financial statements of Ascension Health Alliance d/b/a Ascension, which comprise the consolidated balance sheets as of June 30, 2018 and 2017, and the related consolidated statements of operations and changes in net assets, and cash flows for the years then ended, and the related notes to the consolidated financial statements.

#### Management's Responsibility for the Financial Statements

Management is responsible for the preparation and fair presentation of these financial statements in conformity with U.S. generally accepted accounting principles; this includes the design, implementation and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free of material misstatement, whether due to fraud or error.

#### Auditor's Responsibility

Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

1809-2861252



### **Opinion**

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Ascension Health Alliance d/b/a Ascension at June 30, 2018 and 2017, and the consolidated results of its operations and its cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

Ernst + Young LLP

September 12, 2018

4

# Consolidated Balance Sheets (Dollars in Thousands)

	Jun	e 30,
	2018	2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 850,958	\$ 857,605
Short-term investments	83,166	103,857
Accounts receivable, less allowance for doubtful accounts		
(\$1,384,294 and \$1,316,163 at June 30, 2018 and 2017, respectively)	3,163,172	2,758,554
Inventories	414,169	354,041
Due from brokers (see Notes 4 and 5)	91,919	197,195
Estimated third-party payor settlements	129,693	133,715
Other (see Notes 4 and 5)	780,713	762,900
Total current assets	5,513,790	5,167,867
Long-term investments (see Notes 4 and 5)	19,404,559	16,999,371
Property and equipment, net	10,597,730	9,182,978
Other assets:		
Investment in unconsolidated entities	1,139,306	1,196,651
Capitalized software costs, net	793,322	880,819
Other (see Notes 4 and 5)	1,078,905	892,739
Total other assets	3,011,533	2,970,209
Total assets	\$ 38,527,612	\$ 34,320,425

Continued on next page.

# Consolidated Balance Sheets (continued) (Dollars in Thousands)

	June 30,			•
		2018		2017
Liabilities and net assets				
Current liabilities:				
Current portion of long-term debt	\$	100,919	\$	298,270
Long-term debt subject to short-term remarketing arrangements*		738,770		999,785
Accounts payable and accrued liabilities (see Notes 4 and 5)		2,915,838		2,742,377
Estimated third-party payor settlements		683,229		480,694
Due to brokers (see Notes 4 and 5)		253,264		115,783
Current portion of self-insurance liabilities		288,975		206,787
Other		407,496		340,756
Total current liabilities		5,388,491		5,184,452
Noncurrent liabilities:				
Long-term debt (senior and subordinated)		7,123,611		5,699,440
Self-insurance liabilities		756,028		513,010
Pension and other postretirement liabilities		914,045		1,318,331
Other (see Notes 4 and 5)		1,227,680		1,191,068
Total noncurrent liabilities	1	0,021,364		8,721,849
Total liabilities	-	5,409,855		13,906,301
Net assets:				
Unrestricted				
Controlling interest	2	0,446,065		17,933,923
Noncontrolling interests		1,930,466		1,798,361
Unrestricted net assets	_	2,376,531		19,732,284
Temporarily restricted		508,900		468,938
Permanently restricted		232,326		212,902
Total net assets	2	3,117,757		20,414,124
Total liabilities and net assets	\$ 3	8,527,612	\$	34,320,425

<sup>\*</sup>Consists of variable rate demand bonds with put options that may be exercised at the option of the bondholders, with stated repayment installments through 2047, as well as certain serial mode bonds with scheduled remarketing/mandatory tender dates occurring prior to June 30, 2019. In the event that bonds are not remarketed upon the exercise of put options or the scheduled mandatory tenders, management would utilize other sources to access the necessary liquidity. Potential sources include liquidating investments, a drawon the line of credit to taling \$1 billion, and is suing commercial paper. The commercial paper program is supported by \$300 million of the \$1 billion line of credit.

The accompanying notes are an integral part of the consolidated financial statements.

# Consolidated Statements of Operations and Changes in Net Assets (Dollars in Thousands)

		Year Ended June 30,		
	-	2018		2017
Operating revenue:				
Net patient service revenue	\$	22,795,035	\$	22,104,376
Less provision for doubtful accounts		1,129,175		1,083,661
Net patient service revenue, less provision				
for doubtful accounts		21,665,860		21,020,715
Other revenue		1,493,096		1,693,038
Total operating revenue		23,158,956		22,713,753
Operating expenses:				
Salaries and wages		9,407,216		9,301,057
Employee benefits		1,856,103		1,829,642
Purchased services		2,320,700		1,931,021
Professional fees		1,258,652		1,299,517
Supplies		3,387,222		3,267,278
Insurance		237,275		177,352
Interest		238,981		223,356
Provider tax		531,703		445,791
Depreciation and amortization		1,132,378		1,083,684
Other		2,518,918		2,415,575
Total operating expenses before impairment,				
restructuring and nonrecurring losses, net		22,889,148		21,974,273
Income from operations before self-insurance				
trust fund investment return and impairment,				
restructuring and nonrecurring losses, net		269,808		739,480
Self-insurance trust fund investment return	-	28,000		43,621
Income from recurring operations		297,808		783,101
Impairment, restructuring and nonrecurring losses, net	-	(193,047)		(230,407)
Income from operations		104,761		552,694
Nonoperating gains (losses):				
Investment return		1,589,337		1,420,160
Contributions from business combinations		734,127		1,120,100
Other		(53,239)		(111,671)
Total nonoperating gains, net	-	2,270,225		1,308,489
	===			2,2 00,103
Excess of revenues and gains over expenses and losses		2,374,986		1,861,183
Less noncontrolling interests		213,948		222,266
Excess of revenues and gains over expenses				
and losses attributable to controlling interest		2,161,038		1,638,917
, ·—-o		_, , 0		, -,

Continued on next page.

# Consolidated Statements of Operations and Changes in Net Assets (continued) (Dollars in Thousands)

	Year Ended June 30,			
		2018		2017
Unrestricted net assets, controlling interest:				
Excess of revenues and gains over expenses and losses	\$	2,161,038	\$	1,638,917
Transfers to sponsors and other affiliates, net		(5,189)		(5,062)
Net assets released from restrictions for property acquisitions		51,458		92,104
Pension and other postretirement liability adjustments		313,638		(301,182)
Change in unconsolidated entities' net assets		1,612		8,039
Other		5,740		2,795
Increase in unrestricted net assets, controlling interest,				
before gain (loss) from discontinued operations		2,528,297		1,435,611
(Loss) gain from discontinued operations		(16,155)		226
Increase in unrestricted net assets, controlling interest	-	2,512,142		1,435,837
Unrestricted net assets, noncontrolling interests:				
Excess of revenues and gains over expenses and losses		213,948		222,266
Distributions of capital		(149,990)		(139,477)
Contributions of capital		92,301		285,894
Membership interest changes, net		(27,653)		210
Contributions from business combinations		5,478		210
Other		(1,979)		24
Increase in unrestricted net assets, noncontrolling		(1,575)		24
interests		132,105		368,917
<del></del>		132,103		300,917
Temporarily restricted net assets, controlling interest:				
Contributions and grants		102,954		123,594
Investment return		22,795		29,410
Net assets released from restrictions		(104,873)		(153,648)
Contributions from business combinations		17,853		_
Other		1,233		1,588
Increase in temporarily restricted net assets, controlling				
interest		39,962		944
Permanently restricted net assets, controlling interest:				
Contributions		6,512		8,046
Investment return		4,603		7,263
Contributions from business combinations		13,497		
Other		(5,188)		77
Increase in permanently restricted net assets, controlling				
interest		19,424		15,386
Increase in net assets		2 702 622		1 001 004
		2,703,633		1,821,084
Net assets, beginning of year	77	20,414,124		18,593,040
Net assets, end of year		23,117,757	\$	20,414,124

 ${\it The\ accompanying\ notes\ are\ an\ integral\ part\ of\ the\ consolidated\ financial\ statements}.$ 

# Consolidated Statements of Cash Flows (Dollars in Thousands)

	Year Ended June 30,		
	2018	2017	
Operating activities			
Increase in net assets	\$ 2,703,633	1,821,084	
Adjustments to reconcile increase in net assets to net cash			
provided by operating activities:			
Depreciation and amortization	1,132,378	1,083,684	
Amortization of bond premiums and debt issuance costs	(18,814)	(19,241)	
Loss (gain) on extinguishment of debt	9,850	(10,907)	
Provision for doubtful accounts	1,133,640	1,086,621	
Pension and other postretirement liability adjustments	(313,638)	301,182	
Contributions from business combinations	(770,955)		
Unrealized gains on investments, net	(506,736)	(624,047)	
Change in fair value of interest rate swaps	(49,019)	(70,119)	
Change in equity of unconsolidated entities	(95,224)	(118,630)	
Gain on sale of assets, net	(34,796)	(250,594)	
Impairment and nonrecurring expenses	11,482	40,482	
Transfers to sponsor and other affiliates, net	5,189	5,062	
Restricted contributions, investment return, and other	(152,401)	(144,085)	
Other restricted activity	(31,988)	18,976	
Distributions (contributions) of noncontrolling interest, net	57,689	(146,417)	
Other	(234)	(234)	
Decrease (increase) in:			
Short-term investments	64,739	11,268	
Accounts receivable	(1,197,269)	(1,114,753)	
Inventories and other current assets	43,202	(57,727)	
Due from brokers	105,276	116,522	
Investments classified as trading	(1,170,443)	(1,282,576)	
Other as sets	(134,160)	(13,502)	
Increase (decrease) in:			
Accounts payable and accrued liabilities	(153,406)	206,615	
Estimated third-party payor settlements, net	31,963	19,880	
Due to brokers	137,481	10,123	
Other current liabilities	35,633	55,323	
Self-insurance liabilities	(30,182)	(13,751)	
Other noncurrent liabilities	(196,950)	(180,709)	
Net cash provided by continuing operating activities	615,940	729,530	
Net cash provided by discontinued operations	14,540	7,513	
Net cash provided by operating activities	630,480	737,043	

Continued on next page.

## Ascension

# Consolidated Statements of Cash Flows (continued) (Dollars in Thousands)

	Year Ended J	une 30,
	2018	2017
Investing activities	-	
Property, equipment, and capitalized software additions, net	\$ (1,170,085) \$	(1,272,212)
Proceeds from sale of property and equipment	15,335	3,830
Distributions from unconsolidated entities, net	208,663	52,990
Net proceeds from sale/acquisition of other assets	298,825	354,933
Net cash used by continuing investing activities	(647,262)	(860,459)
Net cash provided by discontinued operations - investing	16 HE	112,238
Net cash used by investing activities	(647,262)	(748,221)
Financing activities		
Issuance of debt	695,501	1,308,307
Repayment of debt	(789,442)	(1,407,063)
Debt issuance costs paid	(3,091)	(5,989)
Decrease in assets under bond indenture agreements	15,869	498
Transfers to sponsors and other affiliates, net	(5,189)	(10,062)
Restricted contributions, investment return, and other	154,176	140,438
(Distributions) contributions of noncontrolling interest, net	(57,689)	146,417
Net cash provided by financing activities	10,135	172,546
Net (decrease) increase in cash and cash equivalents	(6,647)	161,368
Cash and cash equivalents at beginning of year	857,605	696,237
Cash and cash equivalents at end of year	\$ 850,958 \$	857,605

 ${\it The\ accompanying\ notes\ are\ an\ integral\ part\ of\ the\ consolidated\ financial\ statements}.$ 

**Attachment B-Economic-7** 

**Managed Care Contracts** 

# Insurances Accepted

## 

	Plan	Saint Thomas Health	Saint Thomas Medical Partners
•	Aetna  o Commercial plans only	Ø	Ø
•	Aetna		
	Aetna Medicare Advantage	Ø	Ø
•	AMERIGROUP Community Care  o TennCare	Ø	Ø
•	AMERIGROUP Community Care  o Medicare Advantage	Ø	Ø
•	Alive Hospice	Ø	
•	Ascension - SmartHealth	Ø	Ø
•	Avalon Hospice	Ø	
•	BC/BS of TN (BCBST)  Network P  Network S  BlueCare (TennCare)  TennCare Select  Cover Kids  D-SNP  Blue Advantage (Medicare Advantage)	Ø	Ø

•	Caris Healthcare (Hospice)	Ø	
•	CenterCare Managed Care Programs	Ø	Ø
•	<ul> <li>CIGNA</li> <li>Commercial plans</li> <li>CIGNA Connect (Exchange Plan)</li> <li>Sure Fit</li> </ul>	Ø	Ø
•	CIGNA Local Plus (Narrow Network)  o STH and STMP do not participate in Cigna Local Plus (Narrow Network)		
	CIGNA HealthSpring  o Medicare Advantage	Ø	<b>Ø</b>
•	Clover  o Medicare Advantage	Ø	Ø
•	Community Health Plan (fka Americhoice)  o TennCare	Ø	Ø
•	CorVel Corporation (Workers' Compensation)	Ø	Ø
•	Coventry Health Care	Ø	Ø
•	FOCUS Healthcare Management (Workers' Compensation)	Ø	Ø
•	Humana Health Care Plans  o Commercial Plans o Medicare Advantage o POS (Narrow Network)	Ø	Ø
•	KY Medicaid  o Standard Medicaid	Ø	

- Standard KY Medicaid is accepted by Saint Thomas Midtown, West and Rutherford only. Saint Thomas Health will work with each Managed Care Organization on a case-by-case basis.
- o Humana Core Source Currently Contracted

•	MultiPlan	Ø	Ø
۰	National Rural Electric Cooperative Association Group	Ø	
•	Nexcaliber (fka Associated Administrators Group, Inc.)	Ø	
•	NovaNet	Ø	Ø
•	OccuComp (Workers' Compensation)	$\varnothing$	
•	Odyssey Healthcare (Hospice)	Ø	
•	Oscar  o Individual/Exchange	Ø	Ø
•	Prime Health  o Workers' Compensation o Commercial Network	Ø	Ø
•	Private Healthcare Systems (PHCS)	Ø	Ø
•	TennCare	Ø	Ø
•	Tennessee Division of Rehabilitation Services	Ø	
•	TriCare for Life	Ø	Ø

۰	TRICARE Prime		
	o Humana Military	Ø	Ø
•	TRICARE East  o Humana Military	Ø	Ø
•	TriWest - VAPC3 and Choices	Ø	Ø
٠	United Behavioral Health (UBH)	Ø	Ø
•	United Healthcare  o Commercial plans o Medicare Advantage plans	Ø	Ø
•	USA Managed Care Organization	Ø	
•	VHAN (Vanderbilt Health Affiliated Networks <ul><li>Saint Thomas Midtown Hospital</li><li>Saint Thomas Rutherford Hospital</li></ul>	<b>Ø</b>	
•	Wellcare / Windsor HealthCare  o Medicare Advantage	Ø	Ø

**Attachment B-Quality-2C** 

**Hospital Accreditation** 



August 3, 2018

Fahad Tahir, BBA, MBA President and CEO Saint Thomas West Hospital 4220 Harding Road Nashville , TN 37205 Joint Commission ID #: 7891 Program: Hospital Accreditation Accreditation Activity: 60-day Evidence of Standards

Compliance

Accreditation Activity Completed: 8/3/2018

Dear Mr. Tahir:

The Joint Commission is pleased to grant your organization an accreditation decision of Accredited for all services surveyed under the applicable manual(s) noted below:

#### Comprehensive Accreditation Manual for Hospital

This accreditation cycle is effective beginning May 12, 2018 and is customarily valid for up to 36 months. Please note, The Joint Commission reserves the right to shorten or lengthen the duration of the cycle.

Should you wish to promote your accreditation decision, please view the information listed under the 'Publicity Kit' link located on your secure extranet site, The Joint Commission Connect.

The Joint Commission will update your accreditation decision on Quality Check®.

Congratulations on your achievement.

Sincerely,

Mark G.Pelletier, RN, MS Chief Operating Officer

Division of Accreditation and Certification Operations



August 03, 2018

Re: # 7891 CCN: #440082

Program: Hospital

Accreditation Expiration Date: May 12, 2021

Fahad Tahir President and CEO Saint Thomas West Hospital PO Box 380, 4220 Harding Road Nashville, Tennessee 37205

Dear Mr. Tahir:

This letter confirms that your May 08, 2018 - May 11, 2018 unannounced full resurvey was conducted for the purposes of assessing compliance with the Medicare conditions for hospitals through The Joint Commission's deemed status survey process.

Based upon the submission of your evidence of standards compliance on August 02, 2018, The Joint Commission is granting your organization an accreditation decision of Accredited with an effective date of May 12, 2018.

The Joint Commission is also recommending your organization for continued Medicare certification effective May 12, 2018. Please note that the Centers for Medicare and Medicaid Services (CMS) Regional Office (RO) makes the final determination regarding your Medicare participation and the effective date of participation in accordance with the regulations at 42 CFR 489.13. Your organization is encouraged to share a copy of this Medicare recommendation letter with your State Survey Agency.

This recommendation applies to the following locations:

Saint Thomas Anticoagulation Monitoring Clinic d/b/a Saint Thomas Anticoagulation Monitoring Clinic 4220 Harding Road, Dan Rudy Cancer Center, Nashville, TN, 37205

Saint Thomas Heart Failure Clinic d/b/a Saint Thomas Heart Failure Clinic 4230 Harding Road, Suite #450 HI,, Nashville, TN, 37205

Saint Thomas Heart Outpatient Cardiac Diagnostic Center d/b/a Saint Thomas Heart Outpatient Cardiac Diagnostic Center 4230 Harding Road, Suite #325 HI, Nashville, TN, 37205

Saint Thomas Heart Outpatient Cardiac Imaging Center d/b/a Saint Thomas Heart Outpatient Cardiac Imaging Center 100 Physician's Way, Suite #305, Lebanon, TN, 37090

www.jointcommission.org

**Headquarters** 

One Renaissance Boulevard Oakbrook Terrace, IL 60181 630 792 5000 Voice



Saint Thomas Heart Transplant Clinic d/b/a Saint Thomas Heart Transplant Clinic 4230 Harding Road, Suite #450 HI, Nashville, TN, 37205

Saint Thomas Kidney Transplant Clinic d/b/a Saint Thomas Kidney Transplant Clinic 4220 Harding Road, Suite 401, Nashville, TN, 37205

Saint Thomas West Hospital d/b/a Saint Thomas West Hospital 4220 Harding Road, Nashville, TN, 37205

Please be assured that The Joint Commission will keep the report confidential, except as required by law or court order. To ensure that The Joint Commission's information about your organization is always accurate and current, our policy requires that you inform us of any changes in the name or ownership of your organization or the health care services you provide.

Sincerely,

Mark G. Pelletier, RN, MS Chief Operating Officer

Mark Pelletai

Division of Accreditation and Certification Operations

cc: CMS/Central Office/Survey & Certification Group/Division of Acute Care Services CMS/Regional Office 4 /Survey and Certification Staff

**Attachment B** 

Physician CVs



# Dante J. Graves, M.D.

1473 Willowbrook Circle Franklin, TN 37069 Phone: (615) 347-7337 dantegraves a comeast.net

Saint Thomas Heart 4230 Harding Road, Ste. 330 Nashville, TN 37205 (615) 269-4545

BOARD CERTIFICATIONS
Cardiovascular Medicine

YEAR STARTED 1994

**PREPARATORY** 

Western Kentucky University Bachelor's Degree, Biology; Magna Cum Laude

MEDICAL SCHOOL

University of Louisville in Kentucky M.D.

**INTERNSHIP** 

Emory University School of Medicine. Atlanta Georgia

RESIDENCY

Emory University School of Medicine. Atlanta Georgia

**FELLOWSHIP** 

Emory University School of Medicine, Atlanta Georgia Focus in Nuclear Cardiology

**APPOINTMENTS** 

Director, Non-Invasive Cardiology, Saint Thomas Hospital

Dante J. Graves, M.D. Curriculum Vitae

American Society of Nuclear Cardiology
American Society of Echocardiography
Tennessee Medical Association
American College of Cardiology (ACC)
Fellowship Award, F.A.C.C.
Treasurer, TN State ACC Chapter 2006

#### **ACADEMIC AWARDS**

Alpha Epsilon Delta Honor Society
Phi Kappa Phi Honor Society
Chairman's Letter for Outstanding Medical Intern
Chairman's Letter for Outstanding Medical Resident

#### **PUBLICATIONS**

Petracek M, Shuman T, Pirolo J, Tedder M, Ball S, Graves D. "Use of Toronto stentless porcine valve in patients with aortic dilatation", Seminars in Thoracic and Cardiovascular Surgery 11(4): 74-78,1999

Graves, Dante J., Wenger, Nanette K., and Clark, W. Scott. 1994 "Lack of excessive bleeding risk in elderly patients receiving long-term oral anticoagulation" (abstract).

Palevo, Gregory PhD., Graves, Dante M.D., Meece, Rick R.D.C.S., "Evaluation of structured exercise training algorithm in subjects with moderate to severe heart failure". (abstract)

#### **CLINICAL INTERESTS**

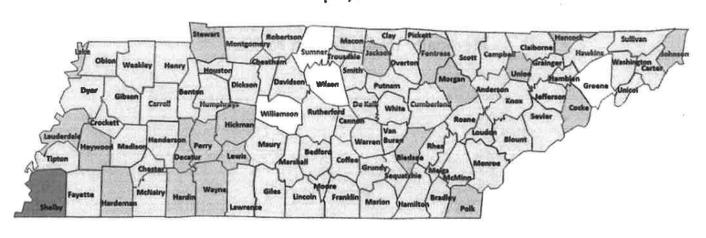
Dobutamine and Exercise Stress Echocardiography
3D Echocardiography in Clinical Practice & Research
Transesophageal Echocardiography
Diagnostic Cardiovascular Angiography
Nuclear Cardiology (thallium scintigraphy, sestamibi imaging)
Issues in anticoagulant therapy
Atrial Fibrillation
Telephonic and Network Medicine

## Attachment B

**Medically Underserved Areas** 



## Federal Health Professional Shortage Areas Primary Care April, 2018



Designation: Whole County Low-Income Population Partial Low-Income Population Whole County Geographic

Data Source: Health Resources and Services Administration, U.S. Department of Health and Human Services, 2018

## **Attachment B**

**Heart Disease Table** 

# NUMBER OF DEATHS FROM DISEASES OF THE HEART WITH RATES PER 100,000 POPULATION, BY RACE, TENNESSEE RESIDENT DATA, 2017

ATTENDED.	TOTAL		WHITE		BLACK	
COUNTY	NUMBER	RATE	NUMBER	RATE	NUMBER	RATE
STATE	16,012	238,4	13,693	259.5	2,225	193.8
ANDERSON	229	300.3	222	317.5	6	
BEDFORD	113	234.8	102	242.8	11	
BENTON	83	519.0	80	527.2	2	
BLEDSOE	30	203.8	29	216.8		
BLOUNT	237	182.4	232	190.2	2	
BRADLEY	275	260.5	262	272.5	11	203.5
CAMPBELL	146	368.2	146	377.5		
CANNON	50	351.6	49	359.7	1	
CARROLL	139	498.9	131	542.1	5	
CARTER	170	301.0	167	306.6	1	
CHEATHAM	85	210.7	84	218.3	1	
CHESTER	50	292.0	46	306,0	4	
CLAIBORNE	111	351.0	111	364.6		
CLAY	29	375.9	29	390.2		
COCKE	190	534.4	184	544.2	6	-
COFFEE	203	368.9	199	391.0	4	
CROCKETT	79	545.7	68	567.3	11	
CUMBERLAND	163	275.9	163	284.9		
DAVIDSON	1,220	176.5	872	193.4	334	173.4
DECATUR	50	425.5	45	404.8	5	175.5
DEKALB	61	307.5	60	318.2	1	
DICKSON	157	297.0	146	298.2	10	
DYER	162	432.5	146	470.1	15	283.1
FAYETTE	108	269.7	78	277.0	29	261.9
FENTRESS	55	303.4	55	310.2	20	201,5
FRANKLIN	147	352.9	135	354.0	12	
GIBSON	196	399.1	170	436.6	24	264.7
GILES	102	346.9	91	358.5	11	204.7
GRAINGER	61	263.5	61	270.8	- 1	18
GREENE	226	328.5	222	337.8	4	
GRUNDY	51	381.5	51	392.9	- 4	
HAMBLEN	166	258.3	158	268.6	6	
HAMILTON	896	247.8	710	258.9	182	257.7
HANCOCK	24	364.8	24	373.4	102	ZJI-I
HARDEMAN	79	310.4	58	409.2	20	187.2
HARDIN	138	533.9	131	539.8	7	107.2
HAWKINS	187	331.2	184	338.1	3	
HAYWOOD	63	358.6	34	408.2	29	326.2
HENDERSON	83	299.1	77	309.8	4	320.2
HENRY	123	379.0	116	399.9	7	
HICKMAN	50	201.1	48	208.6	2	
HOUSTON	34	413.7	32	414.8	2	-
HUMPHREYS	82	443.5	77	414.8	4	
JACKSON	36		36	316.7	- 4	
		308.1				
JEFFERSON	140	260.2	136	264.9	4	
KNOX	58 891	328.1 192.9	55 801	323.8 201.5	3 86	208.1

3 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -	TOTAL		WHITE		BLACK	
COUNTY	NUMBER	RATE	NUMBER	RATE	NUMBER	RATE
LAKE	19	254.4	16	312.7	3	
LAUDERDALE	83	328.4	57	355.2	26	307.
LAWRENCE	115	265.0	113	272.2	2	
LEWIS	40	332.6	40	348.3	- 1	
LINCOLN	113	334.8	109	360.4	4	
LOUDON	143	274.2	141	283.0	1	
MCMINN	167	315.8	160	326.4	4	
MCNAIRY	110	422.9	106	444.9	4	
MACON	64	265.8	63	273.4		
MADISON	264	270.4	176	305.1	86	233.
MARION	107	376.4	99	373.6	8	200.
			72	242.8		
MARSHALL MAURY	82 183	249.0 198.6	166	213.3	10	454
					1/	154.
MEIGS	37	306.7	37	320.0		
MONROE	119	257.4	118	269.3	1	
MONTGOMERY	246	122.9	193	135.1	48	117.
MOORE	19	297.9	19	313.9	- 1	
MORGAN	51	235.8	51	250.5	-	
OBION	101	332.5	95	360.6	6	
OVERTON	61	277.2	61	284.2	-	
PERRY	29	363.2	29	387.3	-	
PICKETT	21	415.0	20	•		
POLK	60	358.1	60	370.5	-	
PUTNAM	193	248.5	190	261.4	2	
RHEA	118	360.9	117	377.6	1	
ROANE	184	347.0	179	357.6	4	
ROBERTSON	169	240.8	153	243.7	16	300.
RUTHERFORD	445	140.3	388	157.3	51	104.
SCOTT	63	286.6	63	292.0		
SEQUATCHIE	43	291.8	42	295.1	1	
SEVIER	244	249.9	244	262.4	-	
SHELBY	1,842	196.6	888	229,8	937	184.7
SMITH	38	193.5	37	197.6	1	
STEWART	38	284.7	38	301.6	-	
SULLIVAN	518	329.6	499	334.0	18	
SUMNER	387	210.8	362	222.6	23	164.1
TIPTON	156	254.2	126	263.1	30	263.3
TROUSDALE	19	188.5	14	161.0	5	
UNICOI	59	332.3	59	340.2	-	
UNION	63	324.2	63	331.8	-	
VAN BUREN	12	210.1	12	214.7		
NARREN	103	253.4	99	261.2	4	
WASHINGTON	332	259.8	319	272.3	10	179.
WAYNE	54	326.0	54	354.4	-	
WEAKLEY	74	222.0	71	239.0	3	
WHITE	70	261.5	70	273.4		
WILLIAMSON	301	133.0	286	141.9	13	128.6
WILSON	222	162.7	203	167.5	17	176.6

TOTAL MAY INCLUDE EVENTS WITH RACE OTHER THAN WHITE OR BLACK, OR RACE NOT STATEO.

\* RATE IS NOT DISPLAYED ACCORDING TO THE TENNESSEE DEPARTMENT OF HEALTH GUIDELINES FOR RELEASE OF AGGREGATE DATA TO THE PUBLIC

4 COUNT IS NOT DISPLAYED ACCORDING TO THE TENNESSEE DEPARTMENT OF HEALTH GUIDELINES FOR RELEASE OF AGGREGATE DATA TO THE PUBLIC

SOURCE: TENNESSEE DEPARTMENT OF HEALTH, DIVISION OF VITAL RECORDS AND STATISTICS

# Attachment C

**Support Letters** 

**Attachment C** 

**Support Letters** 





September 10, 2019

Logan Grant, Executive Director Health Services and Development Agency Andrew Jackson State Office Building 502 Deaderick Street, 9<sup>th</sup> Floor Nashville, TN 37243

RE: Certificate of Need Application – Ascension Saint Thomas West Cardiac PET/CT Scanner

Dear Mr. Grant:

I support the Certificate of Need application filed by the Ascension Saint Thomas West Hospital to initiate cardiac PET/CT scanning capabilities. I am Andrew O. Zurick III, MD.

I have been practicing in Nashville for 8 years, as an Imaging Cardiologist. At the Ascension Saint Thomas West Hospital, I typically treat patients with suspected or known coronary artery disease (CAD) who would benefit tremendously from the replacement of cardiac imaging equipment which has reached the end of its useful life with a cardiac PET/CT scanner. Advancing the imaging capabilities at Ascension Saint Thomas West Hospital, provides the opportunity to meet the needs of a boarder group of patients, ensuring accurate studies, and avoidance of misleading interpretations that result in repeated studies, delays in care and increased costs.

Moreover, Ascension Saint Thomas currently operates the State's largest cardiovascular program. Providing advanced imaging capabilities that align with clinical guidelines allows for safer patient diagnosis and reduced the overall cost of care, all of which is synonymous with Ascension Saint Thomas' values. Because of the benefits of cardiac PET imaging, several independent physician organizations, payers and scientific research agencies have recognized cardiac PET/CT scanning as a superior imaging choice for the CAD patient population.

Approval of the project will improve the quality of cardiac imaging available to patients at Ascension Saint Thomas. This project is at the heart of what makes the cardiovascular program a top choice for Tennesseans. For these reason, I humbly urge the members of the Health Services and Development Agency to approve this project.

Sincerely,

Andrew O. Zurick H, MD, FASE, FACC, FSCMR Medical Director of Cardiovascular CT & MRI

Ascension St Thomas West Hospital

Nashville, TN



September 10, 2019

Logan Grant, Executive Director Health Services and Development Agency Andrew Jackson State Office Building 502 Deaderick Street, 9<sup>th</sup> Floor Nashville, TN 37243

RE: Certificate of Need Application – Ascension Saint Thomas West Cardiac PET/CT Scanner

Dear Mr. Grant:

I support the Certificate of Need application filed by the Ascension Saint Thomas West Hospital to initiate cardiac PET/CT scanning capabilities. I am Dante Graves, Director of Noninvasive Cardiology at St. Thomas Heart West.

I have been practicing in Nashville for 25 years, as an Imaging Cardiologist. At the Ascension Saint Thomas West Hospital, I typically treat patients with suspected or known coronary artery disease (CAD) who would benefit tremendously from the replacement of cardiac imaging equipment which has reached the end of its useful life with a cardiac PET/CT scanner. Advancing the imaging capabilities at Ascension Saint Thomas West Hospital, provides the opportunity to meet the needs of a boarder group of patients, ensuring accurate studies, and avoidance of misleading interpretations that result in repeated studies, delays in care and increased costs.

Moreover, Ascension Saint Thomas currently operates the State's largest cardiovascular program. Providing advanced imaging capabilities that align with clinical guidelines allows for safer patient diagnosis and reduced the overall cost of care, all of which is synonymous with Ascension Saint Thomas' values. Because of the benefits of cardiac PET imaging, several independent physician organizations, payers and scientific research agencies have recognized cardiac PET/CT scanning as a superior imaging choice for the CAD patient population.

Approval of the project will improve the quality of cardiac imaging available to patients at Ascension Saint Thomas. This project is at the heart of what makes the cardiovascular program a top choice for Tennesseans. For these reason, I humbly urge the members of the Health Services and Development Agency to approve this project.

Sincerely

Dante Graves, MD, FACC

Director of Noninvasive Cardiology

St. Thomas Heart West

Nashville, TN



10 September 2019

Logan Grant, Executive Director Health Services and Development Agency Andrew Jackson State Office Building 502 Deaderick Street, 9<sup>th</sup> Floor Nashville, TN 37243

RE: Certificate of Need Application - Ascension Saint Thomas West Cardiac PET/CT Scanner

Mr. Grant:

I am writing this letter to support the Certificate of Need application filed by the Ascension Saint Thomas West Hospital to initiate cardiac PET/CT scanning capabilities. I am Jimmy Kerrigan, MD, an interventional cardiologist at Saint Thomas West.

While this is my first year practicing at Saint Thomas, I spent the last 5 years at the Cleveland Clinic, where I had had access to PET/CT to provide services for my patients and came to know and trust this superior technology for patient evaluation. At the Ascension Saint Thomas West Hospital, I treat patients with suspected or known coronary artery disease (CAD), including chronic total occlusions (CTOs), who would benefit tremendously from the replacement of cardiac imaging equipment which has reached the end of its useful life with a cardiac PET/CT scanner. Especially in the complex coronary and CTO population, evaluating patients with PET/CT provides information that is, often, not otherwise able to be achieved through the technologies we have available. Advancing the imaging capabilities at Ascension Saint Thomas West Hospital, provides the opportunity to meet the needs of a boarder group of patients, ensures accurate studies, and avoids misleading interpretations that result in repeated studies, delays in care and increased costs.

Moreover, Ascension Saint Thomas currently operates the State's largest cardiovascular program. Providing advanced imaging capabilities that align with clinical guidelines allows for safer patient diagnosis and reduced overall cost of care, all of which is synonymous with Ascension Saint Thomas' values. Because of the benefits of cardiac PET imaging, several independent physician organizations, payers and scientific research agencies have recognized cardiac PET/CT scanning as a superior imaging choice for the CAD patient population.

Approval of the project will improve the quality of cardiac imaging available to patients at Ascension Saint Thomas. This project is at the heart of what makes the cardiovascular program a top choice for Tennesseans. For these reason, I humbly urge the members of the Health Services and Development Agency to approve this project.

Sincerely,

Jimmy Kerrigan, MD

Interventional Cardiologist, Saint Thomas Heart, Saint Thomas West

615-308-0190

jimmy.kerrigan@ascension.org





September 11, 2019

Logan Grant, Executive Director Health Services and Development Agency Andrew Jackson State Office Building 502 Deaderick Street, 9<sup>th</sup> Floor Nashville, TN 37243

RE: Certificate of Need Application - Ascension Saint Thomas West Cardiac PET/CT Scanner

Dear Mr. Grant:

I support the Certificate of Need application filed by the Ascension Saint Thomas West Hospital to initiate cardiac PET/CT scanning capabilities. I am Mark Zenker, Director of HCMA Center of Excellence.

I have been practicing in Nashville for 20 years, as an Imaging Cardiology. At the Ascension Saint Thomas West Hospital, I typically treat patients with suspected or known coronary artery disease (CAD) who would benefit tremendously from the replacement of cardiac imaging equipment which has reached the end of its useful life with a cardiac PET/CT scanner. Advancing the imaging capabilities at Ascension Saint Thomas West Hospital, provides the opportunity to meet the needs of a boarder group of patients, ensuring accurate studies, and avoidance of misleading interpretations that result in repeated studies, delays in care and increased costs.

Moreover, Ascension Saint Thomas currently operates the State's largest cardiovascular program. Providing advanced imaging capabilities that align with clinical guidelines allows for safer patient diagnosis and reduced the overall cost of care, all of which is synonymous with Ascension Saint Thomas' values. Because of the benefits of cardiac PET imaging, several independent physician organizations, payers and scientific research agencies have recognized cardiac PET/CT scanning as a superior imaging choice for the CAD patient population.

Approval of the project will improve the quality of cardiac imaging available to patients at Ascension Saint Thomas. This project is at the heart of what makes the cardiovascular program a top choice for Tennesseans. For these reason, I humbly urge the members of the Health Services and Development Agency to approve this project.

Sincerely, Mark Zuhe, MD FACC, FASE

Mark Zenker

HCMA center of Excellence

Imaging Cardiologist

## **Attachment D**

Copy of Published Public Notice Letter of Intent

# Supplemental #1 (Copy)

Saint Thomas
West Hospital
Nashville (Davidson Co.)

CN1909-039

Supplemental #1 **September 30, 2019** 9:29 A.M.

September 27, 2019

Hand Delivered

Phillip M. Earhart Health Services and Development Agency 502 Deaderick Street, 9th Floor Nashville, TN 37243

RE:

Certificate of Need Application CN1909-039

Saint Thomas West Hospital

Dear Mr. Earhart:

Thank you for acknowledging receipt of our application for a Certificate of Need for the initiation of Cardiac PET/CT services at Saint Thomas West Hospital ("STW") on September 13, 2019. This letter and attachments respond to your request for clarification or additional discussion on September 23, 2019. Responses are being submitted in triplicate on Friday, September 27, 2019.

## 1. Section A. Applicant Profile, Item #2

The email address listed for the contact person on page 2 of the application is different from the email listed in the Letter of Intent (LOI). Please clarify.

**RESPONSE:** The correct email address is Lacey.Benford@ascension.org. Page 2 of the application is correct. (Other corrected/revised application pages are presented in Attachment A.)

## 2. Section A. Project Details, Item 4.B.

Please provide an ownership structure organizational chart.

**RESPONSE:** An ownership structure organizational chart is presented in **Attachment** B.

102 Woodmont Blvd • Suite 800 • Woodmont Centre • Nashville, TN 37205 • STHealth.com

## 3. Section A. Project Details, Item 6.B, Plot Plan

The plot plan is noted. However, please indicate the proposed location of the PET/CT and submit a revised plot plan.

<u>Response</u>: A revised plot plan is presented in **Attachment C**. A red "X" marks the location within the existing hospital buildings where the proposed PET/CT unit will be located.

## 4. Section A. Bed Complement Data, Item #10.A

The staffed beds in the second column of the bed complement data chart in the amount of 399 is noted. However, the staffed bed column totals 400. Please clarify.

**RESPONSE:** A corrected page, marked 8-R, is provided in **Attachment A**.

# 5. Section A, Project Details, Item 12 Square Footage and Cost Per Square Footage Chart

It is noted construction cost of \$584.42/SF is above the third quartile cost per square foot for hospital projects of \$403.38/SF. Please discuss why the construction costs for the proposed project is above the third quartile hospital construction costs.

**RESPONSE:** The project involves only 770 square feet of space to be renovated at a cost of \$450,000, which results in what appears to be relatively high cost per square foot. This result is a combination of three factors.

One, high-tech imaging space by its very nature is more costly than general hospital renovations for inpatient and outpatient departments. Imaging space requires expensive shielding, concentrated weight loads and demanding electrical systems. The square footage benchmarks are, therefore, biased toward less complex hospital construction.

Two, general hospital renovation projects typically involve thousands of square feet for inpatient and outpatient departments. With only 770 square feet to be renovated, about the size of four average parking spaces, set up and fixed costs for the cardiac PET/CT unit must be spread across a very small area. There are no economies of scale with this type of project.

Three, the shielding and other installation costs associated with the cardiac PET/CT unit are spread over just 770 square feet. Saint Thomas could have reduced the cost per square foot by expanding the project footprint, but that would have been

unnecessary and wasteful.

## 6. Section A, Project Details, Item 13 (B) ,13 (D), and 13 (E)

A. The draft equipment option to purchase appears to expire November 20, 2019. Please provide a revised draft equipment lease option with a date that is current at least to the scheduled initial HSDA decision date as listed in the Project Completion Forecast Chart.

**RESPONSE:** The equipment option expiration date has been extended. Please see **Attachment D**.

B. It is noted the proposed PET/CT hours of operation will be from 12 am to 12 am. Please clarify if this timeframe represents 24 hours.

**RESPONSE:** Though the PET/CT could be operated at any time throughout the week, it will be staffed for normal operations from 7:00 am until 11:00 pm, seven days per week. A corrected page, marked 11-R, is provided in **Attachment A**.

C. Identify the clinical applications to be provided that apply to the project.

**RESPONSE:** The clinical applications will be focused on cardiology — Rubidium-dosed cardiac PET/CT scans for myocardial stress testing and F-18-dosed myocardial viability testing.

According to the American Heart Association's patient information web pages:

A PET scan of the heart is a noninvasive nuclear imaging test. It uses radioactive tracers (called radionuclides) to produce pictures of your heart. Doctors use cardiac PET scans to diagnose coronary artery disease (CAD) and damage due to a heart attack. PET scans can show healthy and damaged heart muscle. Doctors also use PET scans to help find out if you will benefit from a percutaneous coronary intervention (PCI) such as angioplasty and stenting, coronary artery bypass surgery (CABG) or another procedure.

A PET scan is a very accurate way to diagnose coronary artery disease and detect areas of low blood flow in the heart. PET can also identify dead tissue and injured tissue that's still living and functioning. If the tissue is viable, you may benefit from a PCI or coronary artery bypass surgery.

According to the American Society of Nuclear Imaging<sup>1</sup>:

Recent innovations in cardiac imaging have elevated positron emission tomography (PET) scan as the gold standard of care for patients with suspected or known coronary artery disease CAD. Cardiac PET scanning technology replaces nuclear cameras for cardiac stress testing because PET scanning produces better image quality and leverages numerical precision to identify perfusion defects that might go unnoticed in a traditional SPECT scan. The improved imagining allows for a reduction in misleading diagnosis, repeated studies and delays in care. Additionally, PET scanning results in a favorable throughput because of the type of isotope utilized, which also means less radiation exposure to patients.

## 7. Section B. Need Item 1. (Project Specific Criteria – PET Service) Item #3

A. Please discuss how a cardiac PET/CT is superior to a SPECT General unit for cardiac nuclear medicine studies.

**RESPONSE:** The difference between PET and SPECT is described below in information provided by the National Institute of Biomedical Imaging and Bioengineering at the National Institutes of Health.<sup>2</sup>

The main difference between SPECT and PET scans is the type of radiotracers used. While SPECT scans measure gamma rays, the decay of the radiotracers used with PET scans produce small particles called positrons. A positron is a particle with roughly the same mass as an electron but oppositely charged. These react with electrons in the body and when these two particles combine they annihilate each other. This annihilation produces a small amount of energy in the form of two photons that shoot off in opposite directions. The detectors in the PET scanner measure these photons and use this information to create images of internal organs.

A recent article in the Journal of the American College of Cardiology (Volume 71, Issue 11 Supplement, March 2018), described a study of 3,394 patients and concluded, "there was a significant increase in detection of high-grade obstructive CAD and revascularization within 60 days after transitioning from SPECT to PET."

According to researchers at the Intermountain Medical Center Heart Institute in

<sup>&</sup>lt;sup>1</sup> Referenced from the American Society of Nuclear Imaging, ASNC imaging guidelines/SNMI procedure standard for Positron Emission Tomography (PET) nuclear cardiology procedures. Published online 08 July 2016.

<sup>&</sup>lt;sup>2</sup> See https://www.nibib.nih.gov/science-education/science-topics/nuclear-medicine

Salt Lake City, where the study was undertaken, this study is. "one of the largest of its kind involving PET patients." Key findings of the study are:

- Using PET scans instead of SPECT scans resulted in increased rates of diagnosis of severe obstructive coronary artery disease from 70 percent to 79 percent.
- PET scans were associated with a lower incidence of invasive catheterization without identification of severe coronary artery disease (43% vs 55%).
- Overall, PET more successfully identified patients with severe obstructive CAD and need for revascularization; compared to SPECT, PET scans increased true positives and reduced false positives for severe coronary artery disease.

PET/CT scanners combine both PET and CT scans for increased clinical information. The PET component analyzes cellular functioning while the CT component provides a three-dimensional anatomical perspective of the same area under evaluation. Combining results from both modalities allows attenuation correction to corroborate data and increase clinical confidence in results, for more accurate diagnosis and treatment.

These results are precisely what Saint Thomas Health aims to achieve by its proposed transition from SPECT to PET/CT – more accurate cardiac diagnoses and more effective cardiac interventions.

B. Please clarify if a SPECT General Unit also has a CT component.

**RESPONSE:** By definition, a Single Photon Emission Computed Tomography (SPECT General Unit) also has a CT component.

<sup>&</sup>lt;sup>3</sup> See <a href="https://www.sciencedaily.com/releases/2018/03/180310165832.htm">https://www.sciencedaily.com/releases/2018/03/180310165832.htm</a>

C. What are the plans for the 11 year old SPECT general unit if the proposed PET/CT is approved?

**RESPONSE:** Upon approval and implementation of the proposed cardiac PET/CT project, the SPECT general unit will be decommissioned and removed from the site.

D. Please clarify if the PET/CT will be used exclusively or primarily for cardiac patients.

**RESPONSE:** The proposed cardiac PET/CT will be used exclusively for cardiac patients. There are no plans for other uses (e.g., oncology, neurology) at this time.

## 8. Section B. Need Item 1. (Project Specific Criteria – PET Service) Item #6.B and #6.E

A. Please briefly describe the board certification of Dante J. Graves, MD.

**RESPONSE:** Dr. Graves' curriculum vita is provided in Tab 19 of the CON application.

Dr. Graves is a Fellow with the American College of Cardiology (FACC). Election to Fellowship based on training, board certification and professional accomplishments. Dr. Graves completed fellowship training at Emory University School of Medicine in Atlanta, Georgia, with a focus in nuclear cardiology. Subsequent to his training, Dr. Graves has practiced cardiology for over 20 years.

As a member of the American Society of Nuclear Cardiology, Dr. Graves is qualified to oversee the safe handling of medical isotopes and radiopharmaceuticals.

B. Please provide documentation that attests to the nature and scope of the duties and responsibilities of the physician medical director.

#### RESPONSE:

Rather than medical directorships per se, Saint Thomas Health (STH) has instituted a framework of councils instead. Dr. Graves serves as a voting member of the STH imaging council which oversees operations related to imaging processes throughout the STH network. He was nominated by the committee to serve as the representative for this PET/CT project.

Dr. Graves was appointed the Chair of the Cardiovascular Imaging Council. In this role he is responsible for, among other things, the safe and effective utilization of cardiovascular imaging modalities including nuclear studies. As indicated in **Attachment E**, STH currently holds a radioactive material licensed from the Tennessee Department of Environment and Conservation. Appropriate licensure requirements will be maintained with the PET/CT service as well.

#### 9. Section B. Need Item 1. (Project Specific Criteria – PET Service) Item #8.A

The map of medically underserved areas in Tab 20 is noted. However, please outline the applicant's primary and secondary service area and submit a revised map.

**RESPONSE:** A revised map with the service area is provided in **Attachment F**.

#### 10. Section B, Need, Item 3.

A. The historical utilization of STW patients from JAR is noted. However, the percentages in the last column appear to be incorrect. Please address.

**RESPONSE:** A corrected page, marked 20-R, is provided in **Attachment A**. A minor rounding error has been corrected in an updated table.

B. The projected utilization chart by service area county on page 20 is noted. However, please include a figure that totals 2,100 PET/CT procedures and includes non-service area counties. Please revise and submit a replacement page 21 (labeled as 21R).

**RESPONSE:** A corrected page, marked 21-R, is provided in **Attachment A**.

#### 11. Section B, Need, Item E.

Please complete the following chart. The 2018 HSDA Equipment Registry data is now available.

**RESPONSE:** An updated service area utilization table, including 2018 data, is provided in **Attachment G**.

## 12. Section B, Need, Item F.

A. Please complete the following chart for Years 1-3 of the proposed project.

**RESPONSE:** The requested information is provided below.

Applicant's Projected Utilization - 2020-2022

	Year 1	Year 2	Year 3	% Change
PET Procedures	2,100	2,800	2,820	34.3%
State Health Plan Target Utilization	1,000	1,600	1,600	
% of State Health Plan PET Standard	210%	175%	176%	

B. Provide the details regarding the methodology used to project utilization. The methodology <u>must include</u> detailed calculations or documentation from referral sources, and identification of all assumptions.

**RESPONSE:** Saint Thomas Health is a market leader in cardiac services throughout Tennessee. 2018 Tennessee Hospital Association market share data for the Nashville area places STH at 26.5% of discharges, slightly behind HCA at 28.9% but ahead of Vanderbilt at 10.8%. Yet of these three market share leaders, STH is the only one without PET services.

STH proposes to replace an eleven year-old SPECT unit with a state-of-the-art PET/CT unit at STW, the hub of its cardiovascular service line. SPECT cardiac stress testing at STW declined 6.7% from 2,014 procedures in FY2018 to 1,879 procedures in FY2019. The proposed PET/CT unit is necessary to improve patient care and reverse this decline. As illustrated in **Attachment G**, PET/CT scans among existing service area PET providers have increased 10.1% per year from 2016 to 2018.

From another perspective, in terms of inpatient cardiac services alone, STH reported 10,470 discharges in 2018. At a Year 2 projection of 2,800 procedures, the applicant feels that it can easily project that at least 26.7% of its cardiac inpatients would qualify for a PET/CT procedure. This conversion rate does not consider STH cardiac outpatients nor does it account for service area overall population growth or aging of the population.

As documented at Tab 22 of the CON application, several STW cardiology service line physicians have expressed their support for this project, the needs it will address and the benefits it will provide.

## 13. Section B, Economic Feasibility, Item 1.E Architect's Letter

The architect's letter is noted. However, please revise attesting the physical environment will conform to applicable federal standards, manufacturer's specifications and licensing agencies' requirements including the AIA Guidelines for Design and Construction of Hospital and Health Care Facilities in current use by the

licensing authority.

**RESPONSE:** A revised letter is provided in **Attachment H**.

## 14. Section B, Economic Feasibility, Item 3 and 4 – Historical and Projected Data Charts

Please provide a historical and projected data chart for Saint Thomas West.

**RESPONSE:** Supplemental pages, marked 29-R, 30-R, 32-R and 33-R (Total Facility), are provided in **Attachment A**.

#### 15. Section B, Economic Feasibility, Item 4 – Projected Data Chart

The Projected Data Chart (Project Only) is noted. However, the 2020 Total Operating Expenses and 2021 Total Deductions lines appear incorrect. Please correct and submit a replacement page 32 (labeled as 32R).

**Response:** In each case, two digits were transposed above the subtotals. Replacement pages, marked 32-R and 33-R (Project Only), are provided in **Attachment A**.

## 16. Section B, Economic Feasibility, Item 5.B – Charge Chart

A. Please identify the project's average gross charge, average deduction from operating revenue, and average net charge using information from the Projected Data Charts for Year 1 and Year 2 for Saint Thomas West

**RESPONSE:** A replacement page, marked 34-R, is provided in **Attachment A**.

B. Please compare the proposed PET project's gross charges to the 2018 Gross Charges Per Procedure/Treatment by Quartiles located at the following HSDA web-site:

https://www.tn.gov/content/dam/tn/hsda/documents/quartile-med%20equip.pdf

**RESPONSE:** The Saint Thomas West proposed PET/CT gross charge of \$7,042 in 2020 and 2021 falls between the median (\$5,566.17) and the third quartile (\$7,503.82) as reported in the 2018 Medical Equipment Registry gross charges.

## 17. Section B, Economic Feasibility, Item 6.B – Net Operating Ratio

Please complete the Net Operating Margin Ratio Chart for Saint Thomas West.

**RESPONSE:** A replacement page, marked 36-R, is provided in **Attachment A**.

#### 18. Section B, Economic Feasibility, Item 7 – Payor Mix Chart

A. Charity care in the amount of \$147,876 in the Project Only Payor Mix Chart is noted. However, charity care is \$275,752 in the Projected Data Chart. Please clarify.

**RESPONSE:** \$295,752 is the correct value in both line items. A replacement page, marked 37-R, is provided in **Attachment A**.

**B.** Please complete the payor mix chart for the Saint Thomas West.

**RESPONSE:** A replacement page, marked 37-R, is provided in **Attachment A**.

## 19. Section B, Quality Standards, Item 2.C – Accreditation, Certification and Licensure Chart

Please clarify if the applicant will be licensed or registered by the Tennessee Department of Environment and Conservation for radiological pharmaceuticals.

<u>RESPONSE</u>: As indicated in **Attachment E**, STH currently holds a radioactive material licensed from the Tennessee Department of Environment and Conservation. Appropriate licensure requirements will be maintained with the STW PET/CT service as well.

## 20. Project Completion Forecast Chart

Please complete items #11 and #12 of the Project Completion Chart and submit a replacement page 52.

**RESPONSE:** A replacement page, marked 52-R, is provided in **Attachment A**.

A notarized affidavit accompanies these responses and is found at **Attachment I**. On behalf of Saint Thomas West Hospital, we look forward to having this application deemed complete to start the formal review process.

This information is being submitted in triplicate.

Sincerely,

Lacey Benford
Director, Strategy
Saint Thomas Health

attachments

#### **List of Attachments**

- A. Corrected/Revised Application Pages
- B. Ownership Structure Organizational Chart
- C. Revised Plot Plan
- D. Revised Equipment Option
- E. TDEC Radioactive Materials License
- F. Map of Service Area MUAs
- G. Updated 2018 Service Area Utilization
- H. Revised Architect Letter
- I. Applicant Affidavit

## **Attachment A**

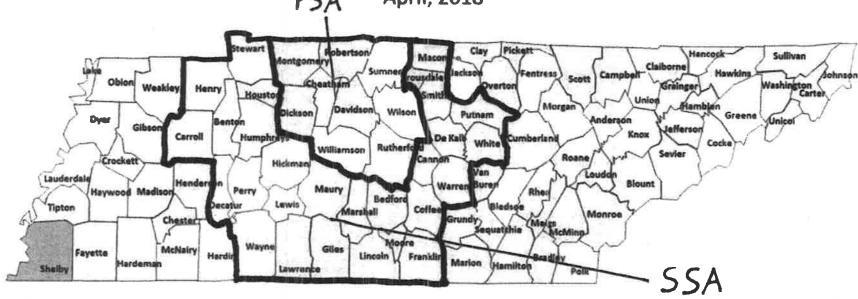
## **Attachment D**

## **Attachment F**



## Federal Health Professional Shortage Areas

**Primary Care** April, 2018 PSA



Designation: Whole County Low-Income Population | Partial Low-Income Population

Whole County Geographic

Data Source: Health Resources and Services Administration, U.S. Department of Health and Human Services, 2018

## **Attachment G**

#### Historical PET Utilization in the Service Area

			2016	2017	2018	<b>'16-'18</b>	2018	2018		
County	Provider	# Units	Procs.	Procs.	Procs.	% change	% of SHP Optimal Standard	Providers V Co (Not by Indiv	Total Resident Procedures to Providers Within Home County (Not by Individual Facility)	
	T	In 2017					(1,600/unit)	#	%	
Coffee	Tennova healthcare = Harton	0.1	46	22	0	-100.0%	0.0%	0	0%	
Davidson	Imaging Alliance - Nashville PET, LLC	1	1,155	1,306	1,312	13.6%	82.0%			
Davidson	Premier Radiology Midtown	1	608	762	931	53.1%	58.2%			
Davidson	Tennessee Oncology, PET Services	1	1,218	1,244	1,340	10.0%	83.8%	2,221	96.82%	
Davidson	TriStar Centennial Medical Center	1	765	974	1,155	51.0%	72.2%			
Davidson	Vanderbilt Medical Center	2	3,852	3,313	3,561	-7.6%	111.3%			
Maury	Maury Regional Medical Center	0.4	604	691	662	9.6%	103.4%	213	43.92%	
Montgom ery	Tennova Healthcare - Clarksville	0.2	334	316	399	19.5%	124.7%	329	47.47%	
Putnam	Cookeville Regional Medical Center	1	656	708	718	9.5%	44.9%	254	71.75%	
Robertson	Northcrest Medical Center	0.2	174	137	185	6.3%	57.8%	133	36.64%	
Rutherfor d	Tennessee PET Scan Center	1	1,932	2,126	2,223	15.1%	138.9%	828	67.98%	
Sumner	Diagnostic Center at Sumner Station	1	265	331	439	65.7%	27.4%	320	40.56%	
Williamso n	Williamson Medical Center	0.5	164	178	1,337	715.2%	167.1%	113	14.87%	
Total	of the second of the	10.4	11,773	12,108	14,262	21.1%	85.7%	N/A	N/A	

Source: Medical Equipment Registry, 8/27/2019

Note: Williamson Medical Center increased from 1/2 Week to Full Week in 2018

## **Attachment H**

## **Attachment I**

#### **AFFIDAVIT**

STATE OF Tennessee	
COUNTY OF _Davidson	
Lacey Benford , b	eing first duly sworn, says that he/she is the
applicant named in this application or his/her/its lav	vful agent, that this project will be completed in
accordance with the application, that the applicant	has read the directions to this application, the
Rules of the Health Services and Development Age	ency, and T.C.A. §68-11-1601, et seq., and that
the responses to this application or any other of	questions deemed appropriate by the Health
Services and Development Agency are true and cor	SIGNATURE/TITLE
Sworn to and subscribed before me this A day	of <u>Septencyer</u> , <u>AOIG</u> a Notary
Public in and for the County/State of Tennes	ssee.
	Johnie Storly NOTARY PUBLIC



My commission expires <u>September</u>

## Supplemental #2 (Copy)

# Saint Thomas West Hospital Nashville (Davidson Co.)

<u>CN1909-039</u>

Supplemental #2 September 30, 2019 4:24 P.M.

September 30, 2019

Hand Delivered

Phillip M. Earhart Health Services and Development Agency 502 Deaderick Street, 9<sup>th</sup> Floor Nashville, TN 37243

RE:

Certificate of Need Application CN1909-039

Saint Thomas West Hospital

Dear Mr. Farhart:

Thank you for acknowledging receipt of our supplemental responses for a Certificate of Need for the initiation of Cardiac PET/CT services at Saint Thomas West Hospital ("STW") on September 30, 2019. This letter and attachments respond to your request for clarification or additional discussion on September 30, 2019. Responses are being submitted in triplicate by 4:00 on Monday, September 30, 2019.

## 1. Section A. Bed Complement Data, Item #10.A

Please provide replacement page 8-R that includes the corrected bed complement data chart.

**RESPONSE:** A corrected page, marked 8-R, is provided in **Attachment A**.

## 2. Section B, Need, Item E.

The following completed chart is noted. However, please contact Alecia Craighead, HSDA Statistician for data to complete the "procedures by residents of PSA" column for each Davidson County PET provider in the following chart.

**RESPONSE:** An updated chart, with data from Alecia Craighead for *each Davidson County PET provider*, is provided in **Attachment B**.

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HICKMAN HOSPITAL

SAINT THOMAS

#### 3. Section B, Need, Item F.

The applicant refers to Attachment G noting scans among service area PET providers have increased 10.1% per year from 2016 to 2018. However, it appears the yearly percentage increase is incorrect. Please clarify.

**RESPONSE:** The table in Attachment G of the Supplemental 1 response reports 2016 – 2018 growth of 21.1%. This *two-year growth rate* of 21.1% is the equivalent of 10.1% *per year* from 2016 to 2018.

## 4. Section B, Economic Feasibility, Item 3 and 4 — Historical and Projected Data Charts

The submitted projected data chart for Saint Thomas West is noted. However, there are now duplicate page numbers for 32-R and 33-R. Please label the Total Facility Projected Data Chart as 33-A and 33-B. In addition, Net Operating Revenue for Year 2020 in the Total Facility Projected Data Chart is incorrect. Please revise.

**RESPONSE:** The Total Facility Projected Data Chart has been relabeled as 33-A and 33-B. Revised pages are provided in **Attachment A**.

Net Operating Revenue for Year 2020 in the Total Facility Projected Data Chart is actually correct. Total Deductions of \$1,908,477 have been restated to the correct amount of \$1,908,447.

This slight change impacted the Total Facility charge chart on page 34-R for 2020, by \$1 for the deduction and average net charge. A revised page is provided in **Attachment A**.

A notarized affidavit accompanies these responses and is found at **Attachment C**. On behalf of Saint Thomas West Hospital, we look forward to having this application deemed complete to start the formal review process.

This information is being submitted in triplicate.

Sincerely,

Lacey Benford Director, Strategy Saint Thomas Health

attachments

## **Attachment A**

## **Attachment B**

#### Historical PET Utilization in the Service Area

		1	TISLOTICA	al PET Utili.	zation in th	e Service A	rea		
			2016	2017	2018	<b>'16-'18</b>	2018	2018	
County		# Units	Procs.	Procs.	Procs.	% change	% of SHP Optimal Standard (1,600/unit)	Total Resident Procedures to Providers Within Home County	
								#	%
Coffee	Tennova healthcare - Harton	0.1	46	22	0	-100.0%	0.0%	0	0%
Davidson	Imaging Alliance - Nashville PET, LLC	1	1,155	1,306	1,312	13.6%	82.0%	419	18.27%
Davidson	Premier Radiology Midtown	1	608	762	931	53.1%	58.2%	299	13.03%
Davidson	Tennessee Oncology, PET Services	1	1,218	1,244	1,340	10.0%	83.8%	467	20.36%
Davidson	TriStar Centennial Medical Center	1	765	974	1,155	51.0%	72.2%	371	16.17%
Davidson	Vanderbilt Medical Center	2	3,852	3,313	3,561	-7.6%	111.3%	665	28.99%
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Montgom ery	Tennova Healthcare = Clarksville	0.2	334	316	399	19.5%	124.7%	329	47.47%
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Γotal	J. 94 T. JEZES T. T.	10.4	11,773	12,108	14,262	21.1%	85.7%	N/A	N/A

Source: Medical Equipment Registry, 8/27/2019

Note: Williamson Medical Center increased from 1/2 Week to Full Week in 2018

## **Attachment C**

## **AFFIDAVIT**

STATE OF TENNESSEE
COUNTY OF <u>Davidson</u>
NAME OF FACILITY:Ascension Saint Thomas West Hospital
I, Lacey Benford after first being duly sworn, state under oath that I am the
applicant named in this Certificate of Need application or the lawful agent thereof, that I
have reviewed all of the supplemental information submitted herewith, and that it is true,
Signature Fitle
Sworn to and subscribed before me, a Notary Public, this the 30 day of 10 day of 2010, witness my hand at office in the County of 2010 State of Tennessee.
NOTARY PUBLIC  My commission expires Suptember 7, 3019.
Wy commission expires OCION 1001 1 , OIOI 1 .

HF-0043

Revised 7/02

